Publications Mail Registration No. 5363
Halifax, N.S.

THE NOVA SCOTIA MEDICAL JOURNAL

VOLUME 71 - NUMBER 4

The Journal is published bi-monthly by
The Medical Society of Nova Scotia
5 Spectacle Lake Drive
City of Lakes Business Park
Dartmouth, Nova Scotia
B3B 1X7
Phone (902) 468-1866
Fax: (902) 468-6578
and printed by
McCurdy Printing & Typesetting Limited

GUEST EDITORIAL

Diagnostic Imaging in the 1990s

A SPECIALTY EVOLVES

Gregory J. Butler,* MD, FRCPC

Guest Editor

As physicians, we are experiencing one of the more difficult times in the history of our profession. We continue to offer our greatest efforts on behalf of our patients, while struggling painfully with the economic realities which now affect every aspect of our personal and professional lives.

While there is yet no visible relief to our current difficulties on the horizon, we can take great consolation and pride in the things which largely brought us in to the profession of medicine in the first place . . . the art and the science.

Radiology is, by anyone's standards, a rapidly changing and challenging field. Technological advances, made available through ongoing improvements in equipment design and innovative new ways of looking at disease, keep radiologists both absorbed and mindful of the responsibility to keep abreast. We take great pride in working along with our clinical colleagues in exploring newer and more efficient ways of detecting and characterizing the illnesses of our patients, thereby helping to initiate early therapy, allay unfounded fears, and guide the clinician/patient team toward recovery.

We are fortunate in this small province to enjoy both a base of modern equipment and a complement of over 70 certified radiologists who provide radiologic consultation to all of the province's major hospitals. Our university faculty enjoys national academic prominence, and our professor an increasing international profile.

We have put together this issue of *The Nova Scotia Medical Journal* to update the practitioner on the accuracies, pitfalls and availability of the latest imaging technology. The authors are all recognized authorities and have been asked to be brief and practical in their presentations.

We hope you find this overview of diagnostic imaging useful and timely. □

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Introduction to Radiology

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Wilhelm Conrad Roentgen was the Professor of Experimental Physics and Director of the Institute of Physics at the University of Wurzburg in Bavaria in 1895, when he discovered the X-ray. His first paper on the subject was entitled "Ueber eine neue Art von Strahlen" – On a New Kind of Rays. It is doubtful that Roentgen would fully realize the impact of his discovery at that time, but in 1901 he was the first recipient of the Nobel Prize for Physics. Radiology societies throughout the world are now planning the 100th Anniversary celebrations for 1995.

The specialty of Radiology has seen very rapid growth and development since that discovery. In the early years, X-rays were used for diagnosis as well as for radiotherapeutic procedures. In the last 15 to 20 years, we have seen the introduction of many new technologies for imaging the human body. Nuclear Medicine became almost a subspecialty within itself and presented a new method of imaging which provided not only anatomical details but, in addition, provided the ability to obtain metabolic information. Diagnostic ultrasound was a new technology which provided anatomical information without the use of potentially dangerous X-rays. With marked improvements in the technology, imaging could be carried out in real time. Angiographic imaging capabilities have become common in X-ray departments, and this has been enhanced with the introduction of digital subtraction angiography. A major improvement in diagnostic capabilities came with the introduction of *Computer Assisted Tomography* (the CAT scanner). By the late 1970s, a wonderful new imaging technology was introduced, using a powerful magnet and the body's magnetic field with the assistance of computers. This had considerable advantage over the CAT scanner in that it was simple to produce images in any plane and greatly improved imaging of soft tissues, the heart and vascular structures without contrast media. This new technology was called *Magnetic Resonance Imaging.*

Many new interventional techniques were being introduced to Radiology at the same time, usually using imaging technology in guiding and directing these procedures. During the last few years this has seen the introduction of percutaneous transluminal angioplasty, the embolization of bleeding vessels through vascular catheters, the removal of intraluminal calculi percutaneously, the lysis of vascular thrombosis, percutaneous organ biopsies and percutaneous catheter drainage of obstructed ducts and abscesses.

This very rapid growth and development has made the specialty very challenging and exciting, particularly so since these departments now play a major role in the diagnosis and treatment of diseases. Generally, this occurs more expeditiously than ever before and with very little risk or discomfort for the patients. Many of the examinations and interventional procedures can be carried out as outpatients and often inpatient hospitalization is shortened and some surgical procedures eliminated. We take some pride in the fact that Nova Scotians have access to radiology facilities comparable to other high quality health care institutions in Canada.

While these major new developments have made a significant impact in improving patient care, there are many new challenges for the specialty. Rapid revisions have been required for undergraduate and postgraduate training programs at the university. Active Continuing Medical Education (CME) programs for practising radiologists have become essential in order to develop competency in the new technology and interventional techniques. The specialty is challenged in the setting of new standards for training as well as for the quality and safety of practice. It must also take a major responsibility for the most cost effective utilization of radiology departments. Referring physicians must be informed of the appropriate selection of examinations and encouraged to consult radiologists for appropriate assistance and guidance when necessary. □

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Computed Body Tomography, Yesterday, Today and Tomorrow

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In the recent *Royal Commission Report on Health Care* and in subsequent press releases, sweeping condemnations of advances in medical technology have been made repeatedly. Surely, these authors must exclude CT in general, and body scanning in particular, from their criticisms.

The basic CT technology was developed 20 years ago and has been in clinical use for about 15 years. The first C.T. body scanner in Nova Scotia was installed in the Victoria General Hospital, Halifax (VG) in June 1980. There are now units operating in Sydney, New Glasgow, Truro, the Camp Hill Medical Centre (Infirmary), Halifax and the I.W.K. Hospital, Halifax and two at the VG (a body scanner and one new scanner used mainly for neuro work). One new unit should begin operation in Kentville in 1992 and it is anticipated that other Regional Hospitals will acquire machines in the near future.

Body CT has revolutionized Radiology and is here to stay. No other technology, other than perhaps image amplification, has had such a profound, beneficial and lasting effect on Radiologic diagnosis and treatment since Roentgen first discovered X-rays almost 100 years ago. The ability to resolve subtle differences in tissue density (attenuation) led the way to cross-sectional imaging in radiologic diagnosis. It was the first modality to use the digital computer in acquiring and analyzing diagnostic information and led the world of medicine into the age of computers. It was also the first equipment to separate acquisition of imaging data from its display and interpretation – a capacity now shared with other imagers.

CT is basically a "mass finder" and therefore plays a major role in diagnosis, staging, biopsy and treatment planning of neoplastic processes. But its uses go far beyond characterization of masses. They include a primary role in assessment of trauma; joint disorders, and other musculoskeletal lesions including neoplasms; precise control of biopsies; imaging of vascular disorders such as aortic dissection; 3D imaging for reconstructive surgery, quantitative CT for bone densitometry, cine CT for special cardiac imaging and a large spectrum of neurologic disorders related to the head and spine. It is gradually replacing myelography and long ago rendered pneumoencephalography and much of cerebral arteriography obsolete. In addition it is showing increasing value in high resolution studies of interstitial, cystic and bronchiectatic disease in the lungs as well as treatment planning by radiation oncologists.

In practical terms body CT has not only made great contributions to diagnosis and management of disorders previously inaccessible to radiology but has also contributed to a reduction in the necessity for more invasive procedures such as angiography as well as exploratory surgery. All of this has led to an immense improvement in patient care as well as indisputable cost effectiveness. Does CT have any areas of weakness? Of course it does. If a neoplastic process does not produce a mass effect, it may go undetected on CT. In some circumstances other forms of imaging are better (e.g. ultrasound for evaluation of gall bladder and biliary tract). In general, however, CT offers the "best look" currently available at liver, pancreas, kidneys, mediastinum and lungs. Ultrasound is usually performed initially in biliary tract, abdominal aorta, pelvis and of course obstetrics. Due to availability, lower cost, and absence of ionizing radiation, ultrasound may also be the modality of choice for screening in other intraabdominal disease.

Perhaps one measure of the usefulness of body CT in patient management is the demand placed on the scanner by referring physicians. Every effort is made to scan in-patients at the V.G. within 48 hours of the request being received, and outpatients within 2 to 3 weeks. All requests for scans are considered by a Radiologist so that inappropriate use of the equipment is kept to a minimum. If a criticism can be made of imaging today it may be that some patients are overassessed by redundant use of too many types of imaging. It is the goal of the Radiologist to screen requests so that the most direct route to diagnosis is taken. Emergencies are done on the day they are requested and are done after regular hours when necessary. We are able to scan an average of 11 to 12 patients/day or 2800/year. Since installation of the body scanner in the V.G. in 1981, we have scanned more than 32,000 patients using more than 1,000,000 individual sections or scans. The scanner has a proven record of better than 95% operating or "up" time and is "down" for servicing less than 1 day/month.

Most patients (other than those for chest examinations) must take oral contrast medium (e.g. water soluble gastrografin or dilute barium E-Z-CAT) the night before and on the day of the scan. This is to opacify the stomach and bowel which if unopacified can lead to misinterpretation of the scans. In addition, patients are often given intravenous contrast medium during the procedure to "enhance" vascular structures and/or abnormalities and thereby permit more precise diagnosis. With introduction of the modern low osmolar contrast media, risks associated with this are minimized. I.V. contrast media are not given if the patient declines or has a history of significant hypersensitivity.

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All patients are briefed on the procedure prior to scanning so that undue apprehension is avoided. Although this is certainly a "high tech" experience, patients and their welfare are the central focus of each examination.

Great advances are being made in the technology related to body CT imaging. Our body scanner, now in its eleventh year is "out of date" even though it has had several hardware "upgrades" since installation. Most advances have been made not only in image quality but also in reduction of time required for imaging. This is not only important so that more patients can be done more quickly and the waiting period shortened, but also so that radiation exposure to the patient can be reduced. A single body CT examination carries a very acceptable radiation exposure to the patient because of the "thinness" of the X-ray beam. On average, it could be considered equivalent to that received in a barium study. But some patients require repeat scanning to follow exacerbations and remissions of their disorder. Radiation can become a concern under those circumstances – particularly in young people. The latest scanners use a technology referred to as "spiral volumetric CT" in which a continuous scan can be made of the entire thorax or abdomen in just a few seconds. (Fig. 1) This will be most important in seriously ill patients who are unable to breath hold or who must be quickly scanned so that treatment can be implemented without undue delay. It will also reduce the radiation dose for those requiring repeat examinations.

Other innovations in CT scanning include development of smaller, more basic machines that cost only about half the price of a sophisticated large centre scanner; that are relatively easy to install; and that are therefore ideal for Regional Hospitals.

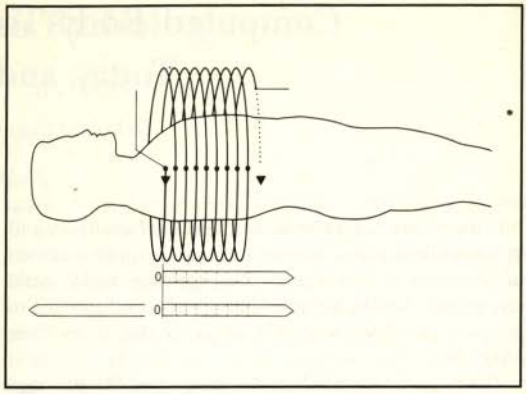

Fig. 1
Spiral volumetric CT.

As digitization of X-ray Departments increases, Electronic Work Stations are likely. These Picture Archiving and Communications Systems (PACS) will permit immediate interpretation from a variety of images via cathode ray tubes and will thereby improve efficiency and decrease the amount of X-ray film used and related costs.

Revolutionary, efficient, cost effective, and safe are all terms applicable to the body scanner but most of all it is a leader in patient care. □

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Vascular and Interventional Radiology

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While attempts at visualizing vessels on radiographs occurred within 20 years of the discovery of X-rays by Roentgen, the development of angiography into a reliable, safe and important part of radiological investigation occurred primarily after the appearance of the image intensifier which allowed procedures to be carried out in a lighted environment.

Approximately 35 years ago, Dr. Sven Seldinger devised a method of introducing a flexible catheter into a vessel without the necessity of first surgically exposing the vessel. The introduction of safe intravascular contrast agents (first ionic compounds and later non-ionic compounds), was the third major development in the field of angiography.

Apart from these pivotal developments, the field has continued to change rapidly with refinements in catheter and guidewire design and with the introduction of other devices and instruments for intravascular use, most of which can be used percutaneously.

The subspecialty of angiography has gradually evolved into vascular and interventional radiology, with many vascular radiologists becoming involved in procedural work requiring radiography and an intravascular approach, and frequently using instruments first developed for angiography. For the purposes of this short review, I will confine my comments to vascular radiological procedures only.

ARTERIOGRAPHY

In general, arteriography procedures can be divided into two groups: a) procedures to evaluate the vessels themselves; and b) procedures to evaluate organs and organ systems using the arterial anatomy as a guide.

When evaluating vessels themselves, the most common procedures include peripheral, carotid, and coronary arteriography – usually to assess the degree of involvement of vascular diseases, the most common of which is atherosclerosis. Other diseases such as fibromuscular dysplasia of renal arteries are occasionally visualized as well.

The examination of organs includes the search for tumors and the extent of tumor involvement, as well as examining aspects of gross anatomy as reflected in the vascular structure of the organ, pathological changes frequently being reflected in changes in its vascular anatomy. While many of the latter examinations have been superseded by less invasive procedures, including computed tomography, ultrasound, magnetic resonance imaging and nuclear medicine studies, frequently important additional information is obtained by arteriography.

VASCULAR INTERVENTIONS

In addition to a study of gross anatomy of an organ or the vascular anatomy by angiography, a wide variety of techniques have been devised to make use of the percutaneous approach to blood vessels.

Angioplasty

The most widely known application of percutaneous catheter techniques is undoubtedly angioplasty. Introduced in 1964 by Dotter and Judkins, the technique as originally devised was used sporadically with mixed results. By 1979 Gruntzig and Hopff had developed a balloon catheter, using a polyvinyl balloon with low compliance, which allowed dilatation of a vessel to a predetermined diameter.

Angioplasty balloons have now been used in a large number of patients in a wide variety of vessels including peripheral vessels, coronary arteries, renal arteries and GI vessels. Successful angioplasty requires training and skill in general vascular techniques. In this environment, while not without some risks, it is generally a safe and reliable technique with considerable savings in costs and discomfort to the patient when compared with appropriate surgical techniques.

The long term results of angioplasty depend upon a number of factors including the immediate result obtained, the vessel involved and the extent of disease present. One advantage is that the technique can be repeated over time without added risks and collateral pathways are undisturbed by the procedure.

The comparison of angioplasty results to those of surgery is difficult for a variety of reasons and few reliable comparisons exist. In general, it can be said that the results of surgery and angioplasty in isolated lesions (in the iliac vessels and femoral arteries for example), is comparable both in the short and long term. When the disease is extensive in these vessels over long segments, the results of surgery would appear to be better.

With specialized catheters, angioplasty of the calf vessels where surgery is often difficult, has led to increased limb salvage in patients with atherosclerosis. This type of disease is frequently associated with diabetes.

In the renal arteries, angioplasty has proved highly successful in non-ostial arterial lesions. Unfortunately, a large proportion of renal artery stenotic lesions occur at the vessel origin where angioplasty is less satisfactory.

While it is still our policy to carry out angioplasty chiefly on inpatients, this procedure requires only a short term admission. The procedures themselves are performed

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under local anaesthesia only. They are, therefore, highly acceptable to patients and, as indicated, are performed at significantly lower cost than vascular surgical procedures.

Drug Infusions and Embolization

Transcatheter introduction of drugs and clotting agents into specific arteries and veins has evolved over time as an important area of angiographic intervention. It began clinically with the use of Vasopressin and similar agents injected into appropriate gastrointestinal vessels, used to control GI bleeding. This has been largely abandoned, however, as it has been found that the agents are as effective when injected intravenously.

The ability to catheterize the arterial supply to a specific organ allows the introduction of chemotherapeutic agents in high concentration to a specific area at a relatively low whole body dose. Similarly, radionuclides may be introduced either for therapy or diagnostic purposes.

Embolization of vessels has proved useful in a wide variety of situations. It is used commonly in hemorrhage secondary to trauma, particularly in the pelvic region, kidneys liver or spleen. In malignant disease, embolization of vessels may be used to control bleeding as in uterine or renal carcinomas or as a means of destroying the vascular supply to a tumor. This is particularly useful in organs with end artery blood supplies and relatively poor collateral flow such as the kidney and the liver.

A wide variety of agents have been used for occluding arterial and venous flow. The commonest include absorbable gelatin powder (Gelfoam), polyvinyl alcohol foam (Ivalon), absolute alcohol autologous blood clot and wire coils with dacron (Gianturco coils). In addition, life-threatening bleeding can often be controlled in the short term by using angioplasty balloon catheters.

Ability to access the blood supply to a specific organ or anatomical area for therapeutic purposes has, to date, been used relatively uncommonly; however, there are indications that this will be used more commonly in the future.

A specific use of drug infusion is the treatment of thrombosis or embolization of peripheral vessels with thrombolytic agents as an alternative to surgery. While not a new technique, complications associated with the procedure using Streptokinase, delayed widespread acceptance. Newer plasminogen activators, most notably TPA (tissue plasminogen activator) and urokinase with a lower incidence of side effects, has led to a greater acceptance of the procedure particularly in recent thrombosis but increasingly as well in long standing (six months or greater) occlusions. On dissolution of thrombus, a stenotic lesion in the vessel requiring angioplasty is frequently found.

As refinements in catheters and delivery systems continue to be made, more and more cases are considered for thrombolytic therapy as an alternative to bypass surgery as the first line attack in peripheral vascular disease. While not the subject of this paper, the use of thrombolytic agents in coronary artery thrombosis is well established.

Vascular Stents

In a continuing effort to develop methods of treating vascular disease by percutaneous methods, a number of vascular stents, designed to maintain lateral force against stenotic vessel walls, have been developed. The Palmaz wire mesh stent is the only device currently approved for use in Canada. It is delivered to the site to be stented, crimped on an angioplasty catheter and expanded by dilatation of the angioplasty balloon. Once expanded, the stent remains at that diameter, thereby preventing recoil of the diseased artery.

Other stents currently in development are approved in other countries and work by different mechanisms but can still be delivered percutaneously.

As frequently happens, stents designed for treatment of atherosclerotic narrowing of vessels have been found to have other usages, particularly in the stenting of biliary ducts when ductal narrowing is present due to various benign diseases or is palliation in malignant disease.

In portal hypertension associated with cirrhosis, portocaval shunts can be produced and maintained within the liver substance itself using vascular stents. A catheter and needle introduced through the internal jugular vein is passed through an hepatic vein. The curved needle is turned anteriorly and advanced into a portal vein. A guidewire is passed through the needle. With removal of the needle, a balloon catheter on which the stent is crimped is passed over the wire and expanded when the stent bridges the space between the portal and hepatic veins.

Other Procedures

Caval Filtration - it has been shown that approximately 90% of clinically important pulmonary emboli arise from the lower limbs or pelvic veins. In circumstances where anticoagulation is contraindicated in patients at high risk for pulmonary embolism or where repeated pulmonary embolism is life threatening, an inferior vena caval filter may be inserted into the vessel percutaneously either from the femoral vein or via the jugular vein should the femoral veins be involved with thrombus. Prior to development of intravascular filters, in these circumstances it was necessary to surgically ligate or plicate the inferior vena cava, a procedure which carried with it some degree of morbidity.

Catheter Retrieval - increasingly, central venous catheter lines are used during the treatment of seriously ill patients in hospitals. It is not infrequent for portions of these catheters to break and drift into the right heart and pulmonary arteries. While these are frequently innocuous, they may serve as a focus of infection or thrombosis. A variety of snares and retrieval instruments have been developed for percutaneous removal of these foreign bodies.

Venous Catheterization - the ability to catheterize specific veins, for example renal and adrenal veins, allows

the possibility of obtaining blood samples for various analyses.

The Future

Angiography has evolved in a wide variety of directions through the years and the scope of percutaneous intravascular procedures continues to broaden. After an initial burst of enthusiasm, laser angioplasty in the treatment of athrosclerotic lesions has fallen into disfavour for the moment, essentially awaiting the development of refinements in laser energy and new intravascular probes.

Intravascular ultrasound as a diagnostic tool is available and therapeutic ultrasound using ultrasound energy to obliterate atherosclerotic plaque is a likely possibility for the future. Various other devices have been developed which are designed to remove plaque from the inner surfaces of critical vessels. These have proved to be useful in specific circumstances and as further refinements in these tools develop their application will unquestionably widen.

SUMMARY

While the indications for angiography have changed over the years and other diagnostic modalities, especially ultrasound, CT, magnetic resonance imaging and nuclear medicine have replaced angiography in a number of situations, the evolution of both the tools and the indications, plus the introduction of therapeutic techniques, make the area of vascular intervention a growing and cost effective way of dealing with a variety of medical problems. There is every indication that the evolution and broadening of the scope of this area will continue in the future.

□

A useful reading list is available from the author.

Call for Nominations - Society Officers
The Medical Society of Nova Scotia

An election for the following positions will be held at The Society's Annual Meeting November 20-21, 1992.

President Elect

Chairman - Executive Committee & General Council
(Currently Dr. Shelagh Leahey -- eligible for re-appointment -- not re-offering)

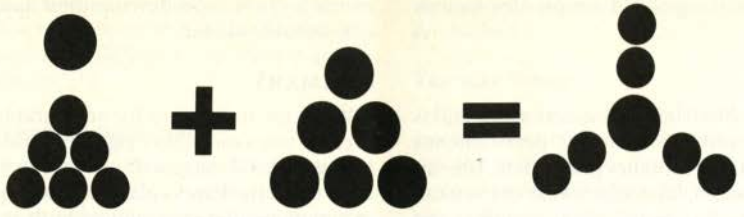
Vice-Chairman - Executive Committee & General Council
(Currently Dr. Anne Houstoun -- ineligible for re-appointment to this position)

Treasurer
(Currently Dr. Ken Langille -- eligible for re-appointment to this position)

Honorary Secretary
(Currently Dr. Renn Holness -- eligible for re-appointment to this position)

Member-at-Large
(Currently Dr. Kim Crawford -- ineligible for re-appointment to this position)

Nominations must be made to the Nominating Committee which consists of the Past Presidents of the Branches of The Society. The Nominating Committee must report its recommendations at least four weeks prior to the Annual Meeting. Nominations should therefore be put before them by the end of September at the latest. Nominations may also be made from the floor provided such nominations are placed in writing in the hands of the Executive Director not less than one week prior to the Annual Meeting. Such nominations must be signed by ten members of The Society in good standing and such nominations must be accompanied by the written consent of the nominee to serve, together with his/her Curriculum Vitae.



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Diagnostic Ultrasound: Clinical Applications

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Over the past decade, there has been a dramatic increase in the number of diagnostic ultrasound examinations performed in Nova Scotia. The ever broadening clinical applications, development of new ultrasonographic techniques such as color flow doppler imaging, endovaginal sonography, and endorectal sonography, more widespread application of doppler studies (eg. doppler ultrasound assessment of deep vein thrombosis and carotid artery disease) as well as the greater accessibility of this technique account for some of this growth.

This increasing utilization of diagnostic ultrasound has many valid motivations. Valuable diagnostic information can be obtained quickly and non-invasively, without the use of ionizing radiation. Other diagnostic studies that are often more invasive and costly are being replaced by ultrasound imaging. Examples of this process are the declines in referrals for IVPs, oral cholecystograms, and carotid digital subtraction angiography, replaced by renal and gallbladder ultrasound and doppler ultrasound studies respectively.

In this review space permits only a superficial discussion of the value of various abdominal ultrasound studies but the following attempts to guide the referring physician towards a logical and pragmatic use of the modality. The discussion is confined to non-obstetrical abdominal ultrasound.

GALLBLADDER AND BILIARY TRACT

Ultrasound has replaced oral cholecystography as the primary investigation of choice of the gallbladder, particularly in the evaluation of suspected stone disease. Its speed, simplicity and ability to view adjacent relevant organs (bile ducts, liver, pancreas) have contributed to this change. Accuracy is in excess of 98% in the diagnosis of gallbladder stones.[1] Although less useful in identifying ductal stones, ultrasound still has a primary role in the investigation of obstructive jaundice.[2] Other imaging procedures including CT or direct cholangiography are often necessary to accurately define both the level and cause of obstruction (most often stone or tumor).

METASTATIC DISEASE

In the case of a known primary neoplasm, it is probably most pragmatic to use diagnostic ultrasound initially in the search for intra-abdominal metastatic disease, particularly taking into account the relatively limited access to CT scanning in Nova Scotia. For liver and splenic metastases this modality is almost as accurate as CT scanning although less so for adrenal, nodal and other secondary metastatic deposits[3] (Fig. 1). If positive for metastatic disease an ultrasound can, therefore, obviate the necessity for other imaging procedures. Redundancy in requesting concurrent ultrasound, CT and nuclear scanning should be avoided.

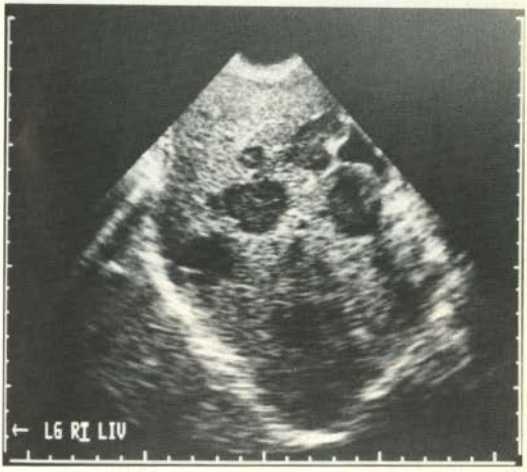

Fig. 1
Sagittal image of the liver demonstrates multiple varying sized hypoechoic liver metastases.

PANCREAS

In acute pancreatitis the pancreas is visualized in as few as 20% of patients due to an associated ileus.[4] Furthermore the pancreas may be sonographically normal in 29% of cases of acute pancreatitis.[5] Ultrasound imaging is of limited value in acute pancreatitis except in its role of identifying biliary stone disease as a causative factor. In the progression of the disease, however, pseudocysts can be identified and monitored.[6] Pancreatic neoplasms can be imaged but not as accurately as with CT.

KIDNEY

Ultrasonography is a valuable diagnostic method in the assessment of renal disease. Hydronephrosis can be easily diagnosed, although identification of its cause and the level of obstruction usually requires contrast studies.[7] Plain film radiography (KUB) or an IVP are the preferred initial methods of evaluating suspected renal calculi, but larger renal calculi (> 3 mm) may be visualized by ultrasound regardless of the chemical composition of the stone[8] (Fig. 2). In patients presenting with hematuria, renal masses (either cystic or solid) may be

From the Department of Diagnostic Ultrasound, Victoria General Hospital, Halifax, N.S.

identified and characterized. Evaluation of hepatic metastases, regional lymphadenopathy, and tumor invasion of either the renal vein or IVC is possible in renal cell carcinoma.[9] In patients with renal failure, either acute or chronic, renal size and morphology can be evaluated and an obstructive etiology confirmed or excluded.

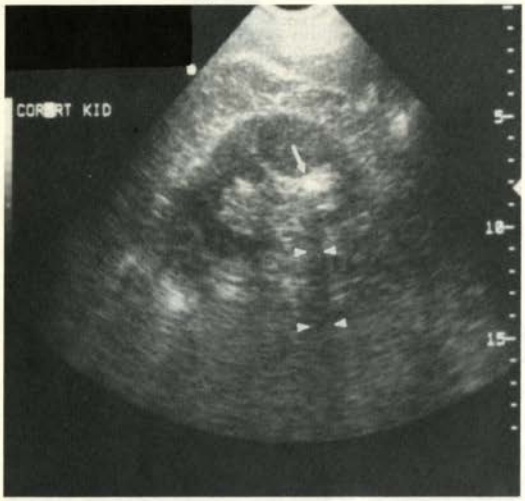

Fig. 2

Coronal image of the right kidney demonstrates an echogenic (arrow) calculus with posterior acoustic shadowing (arrowheads).

AORTA

Abdominal aortic aneurysms are usually readily identified and monitored serially using diagnostic ultrasound. Although complications such as rupture and dissections can also be seen these are better evaluated by CT.[10]

DOPPLER

Duplex doppler ultrasound and, where available, color flow capability, enhances the role of diagnostic ultrasound in many areas. Useful applications of this technology include: evaluation of the portal venous system (Fig. 3), hepatic veins, renal blood supply (particulary in transplants), aortic aneurysm, femoral and IVC thrombotic disease, screening for carotid and peripheral vascular disease and testicular torsion.

INTERVENTIONAL ULTRASOUND

Interventional procedures, directed by real time ultrasound guidance, form a large part of the workload of ultrasound departments in tertiary care hospitals, and to a more limited extent in regional and community facilities. Ultrasound guidance is utilized in part due to the limited availability of CT equipment, but many radiologists prefer ultrasound direction over CT for its speed, flexibility, portability, and real-time capability. Biopsies of intra-abdominal masses (particulary hepatic), renal biopsies, percutaneous nephrostomy diagnostic aspiration and drainage of intra-abdominal fluid collections and cysts under ultrasound direction are all well established techniques. Many of these procedures can be done on an outpatient basis with some post-procedural monitoring.

LIMITATIONS

In general terms, ultrasound studies are of limited benefit in suspected disease of the hollow viscera, evaluation of abdominal pain not specifically organ-directed, and as a "placebo" investigation for a demanding patient. Duplication of other imaging studies and nonindicated follow-up examinations should also be avoided.

CONCLUSION

Abdominal ultrasound, by its noninvasive nature, has become a favoured diagnostic tool of physicians. Both the radiologist and the referring physician have roles to play in minimizing unproductive overutilization of the modality. Referring clinicians should acquire adequate working knowledge of what various ultrasound studies can offer, what their limitations are, and should provide the radiologist with adequate clinical information for his referrals. Radiologists should energetically review all requests for diagnostic ultrasound as he should for all studies he performs. In these times of fiscal restraint we can then hope to gain maximum benefit for our patient population from this rapidly developing and increasingly available imaging modality. □

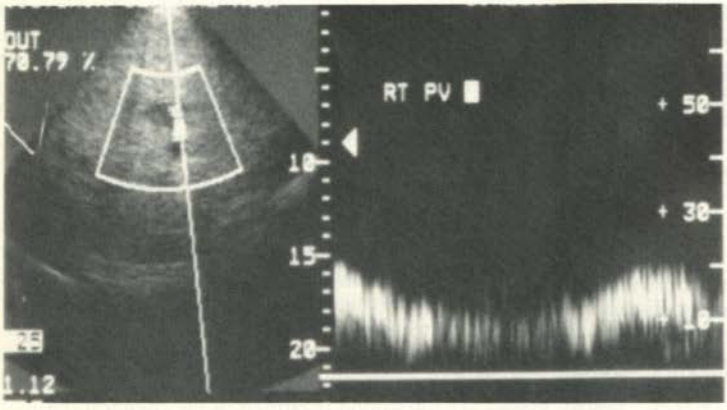

Fig. 3

Doppler analysis of the right portal vein demonstrating normal phasic flow.

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Obstetric Ultrasound – Update 1992*

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During the last 20 years, one of the most significant advances in obstetric management has been the development of obstetric ultrasound.[1] It is now rare for a pregnant woman not to have at least one ultrasound examination. During the fiscal year April 1, 1990 to March 31, 1991, a total of 23,563 obstetric ultrasound examinations were performed in 21 departments of Diagnostic Imaging in Nova Scotia. This is less than the previous years total of 25,858 obstetric ultrasound exams when deliveries were approximately the same (12,652 vs 12,596).[2] Since a significant number of patients who have obstetric ultrasound may go on to have a spontaneous or therapeutic abortion, these pregnancy losses would have to be taken into account when deriving the number of ultrasound examinations per delivery. Regardless, the examination is performed very frequently, so it is important to be aware of the indications, limitations, and effective usage of the modality.

INDICATIONS FOR OBSTETRIC ULTRASOUND EXAMINATION

Uncertain Dates

Any woman who is unsure of her dates, should have an obstetric ultrasound examination to date the pregnancy. The accuracy of the ultrasound estimate of gestational age varies inversely with the gestational age.

During the first trimester, after the embryo has become visible to ultrasound examination (5 to 6 weeks by endovaginal ultrasound or 6 to 8 weeks by transabdominal ultrasound), crown rump measurements can predict gestational age to within plus or minus 3 days, 19 times out of 20.[3] During the third trimester, this accuracy falls even when multiple fetal measurements are used, to plus or minus 3 weeks. Thus, there is a trade-off since most anatomic structures will not be well visualized during the first trimester – even anencephaly cannot be excluded with certainty before 10 or 11 weeks.

Suspected Abnormality

Almost any sign or symptom of abnormality of the pregnancy is an indication for obstetric ultrasound, but the big debate is whether a pregnancy which appears to be progressing normally in every way should have one or more obstetric ultrasound examinations. The Ying side of this argument states that the examination is possibly harmful to the developing fetus, is a strain on the funds available for health care and, other than termination of pregnancy, the ultrasound findings make little difference, since fetal surgery to date has met with limited success. The Yang side of this argument counters quickly that there is no conclusive evidence of harm from diagnostic ultrasound,[4] that the procedure is cost effective, non-invasive and relatively inexpensive, and although the promise of intra-uterine fetal surgery has not lived up to expectations except in some isolated instances, definite progress continues to be made in this area. Furthermore, in conditions such as IUGR effective treatment can be instituted while there is still time.

It has been estimated that only one fourth of the total number of children with congenital anomalies, which comprises 6.5% of all children, have anomalies that are detectable by obstetric ultrasound.[6] Fortunately these are major anomalies such as anencephaly, meningomyelocele, hydrocephalus, hydrops, cystic hygroma,[7] multicystic kidney, diaphragmatic hernia, omphalocele and gastrochisis. Cardiac anomalies,[8] clubfoot and facial clefts are being increasingly detected. Certain chromosomal anomalies such as Trisomy 13, and Trisomy 18 are easily identified, but no firm diagnostic ultrasound criteria have been established that allow the diagnosis or exclusion of Down's Syndrome. When an examination is obtained at approximately 18 weeks and an abnormality is found, there is still time to consider all options. Today it is rare that a couple does not choose termination when a serious anomaly is diagnosed, prior to 24 weeks.[9]

TIMING OF OBSTETRIC ULTRASOUND EXAMINATION

This of course depends on the indication and, if there are signs or symptoms of abnormality, then the examination should be performed as soon as possible. If the examination is being performed because the patient is unsure of her dates, an ultrasound examination will date the pregnancy most accurately if done during the last half of the first trimester. Gestational age should be calculated from the earliest sonogram, and is not changed by the results of subsequent ultrasound examinations. If the examination is a detailed examination primarily to assess the fetus, then it is best done at approximately 18 weeks when all organ systems can be reasonably well visualized. If there is a significant abnormality present, there is still time to consider continuation or termination of the pregnancy. If a major but non-lethal fetal anomaly such as diaphragmatic hernia is diagnosed on ultrasound examination, it is eminently preferable to transport the mother prior to delivery to a tertiary care centre rather than delaying until after the baby has arrived. At 18 weeks gestation, good fetal measurements yield an estimate

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error of fetal age of 7 to 10 days which should be quite adequate in most instances.

GENDER

The gender of most, but not all fetuses can be determined by the mid second trimester. The sex of the male fetus is easier to determine and accuracy is almost 100 percent. Overall, accuracy of determination of gender in the female fetus is over 80 percent, but it varies in the individual case from just a little over 50 percent to times when one is absolutely certain. The sex of the fetus is not looked for unless the mother specifically makes the request or there is a medical indication. If the sex is determined incidentally during the examination, the mother is not informed unless she asks. We do not perform the examination when there is no medical indication to determine the sex of the fetus.

COMPANIONS PRESENT DURING THE EXAMINATION

Both the Grace Maternity Hospital and the IWK Children's Hospital, where all our obstetric ultrasound examinations are performed, are family centered care institutions which means among other things, that family members (and sometimes extended family members) are encouraged to observe and participate in most procedures related to the pregnancy, and the delivery itself. Despite our crowded quarters during the last 10 years, when we have had all three ultrasound machines in one room, we have incorporated this philosophy into our obstetric ultrasound examination, by inviting companions to witness the ultrasound examination.

Initially, some of our radiologists and technologists were apprehensive about having companions present during an examination, However, having once started this practice, we have been surprised how well this has functioned for the majority of families. We have often witnessed the "bonding effect" on parents referred to in the literature.[10] Also for many parents who are apprehensive "seeing is believing", particularly when the news is good. On one hand, when the news is unexpected, as in unexpected twins, family support is immediately available. Also when the news is bad or disastrous, again family support is right there. Beginning in May of this year with the move to larger quarters, there will be optimal privacy for each family since there will be individual examination rooms.

LIMITATIONS

Regarding cephalo-pelvic disproportion, the assessment of the maternal bony pelvis is still not possible even with the most sophisticated ultrasound apparatus. The assessment of anatomy of the embryo during the first trimester is very limited, although the demonstration of circulatory activity is the sine qua non of fetal life. Similarly, an examination for gestational age during the last trimester has such a wide normal variation (plus or minus 3 weeks) that is unlikely to be of any great value in dating the pregnancy. Several formulae based on measurement of various body parts are available to predict the present weight of the growing fetus. Unfortunately even the most complex has a margin of error of approximately 15%.[11] This is not entirely unexpected since detailed, highly accurate, physical measurements of the newborn infant will predict weight only within 8%.[12] The appreciation of IUGR is still a difficult problem and although numerous conventional (at least nine) and Doppler Ultrasound criteria have been proposed for diagnosing IUGR prenatally, none on its own permits confident diagnosis of this condition. Estimated low fetal weight and diminished amniotic fluid volume are still the best ultrasound findings to help in this diagnosis.

CONCLUSION

When there are symptoms or signs suggesting an abnormal pregnancy, then an obstetric ultrasound examination should be obtained as soon as possible. If there is any reasonable doubt as to the reliability of dates, then an obstetric ultrasound examination should be obtained no later than 18 weeks. If this exam is obtained at approximately 18 weeks, then there is the added benefit of a detailed study of fetal structures.

Our experience with obstetric ultrasound during the last 18 years has proved an education in itself. Today we know that in many serious fetal anomalies, the mother may be entirely asymptomatic. It is here that the medical profession and indeed the public are becoming more keenly aware of the benefits of a detailed ultrasound exam at approximately 18 weeks. At this critical stage of development of the baby, if something is wrong, the condition can usually be diagnosed while there is still time for implementation of effective options. □

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Magnetic Resonance Imaging at the Victoria General Hospital

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Magnetic Resonance Imaging (MRI) is a revolutionary new modality which has had an enormous impact on many aspects of medical imaging. Simply, MRI is a method of obtaining exquisite multiplanar images by computing information produced by the interaction of radiofrequency pulses in patients placed in a powerful magnetic field (30,000 x the force of gravity). The various concentrations of hydrogen protons, under the influence of external radiofrequency pulses in the magnetic field, are affected in such a way that they emit pulsed radiofrequency energy or signals which are sampled and computed into images. The intensity of the signals depend on the amount of hydrogen in various tissues. For example, because bone has relatively less hydrogen than fat, the signal intensity of bone is lower than fat. Basically, this produces tissue contrast. There is no ionizing radiation involved.

The principles of MRI have been well known and applied for many years in chemistry and physics, being referred to as *Nuclear Magnetic Resonance*. In the late 1970s it was applied with increasing success to medical imaging. By the early 1980s the industry had progressed to a point where the technology was available and both image quality and examination times had reached a stage where it became clinically useful.

This precipitated a flood of new information requiring research to evaluate new imaging manifestations of many diseases.

The acquisition of MRI at the Victoria General Hospital is, to a great extent, attributable to the efforts of Dr. D.B. Fraser, Professor of Radiology. Negotiations with various manufacturers began in 1981. Presentations to government, hospital and university culminated in approval in principle and formation of a selection committee, with final recommendations in 1985 and purchase in 1986. A Philips 1.5 Tesla unit was chosen at a cost of about two million dollars. One million of this was raised by the VG Foundation. New construction was carried out at the west end of Centennial Building, resulting in a spacious, modern MRI installation. The project was completed and service established in December 1988. This is the only MR imager east of the Province of Québec and service is provided for all of the Atlantic Provinces. To provide the most meaningful information for the maximum numbers of patients, triage of requests and tailoring of examinations are required, due to the limited throughput and great clinical demands.

Figure 1

M.R.I. unit at the Victoria General Hospital. Philips 1.5 Tesla superconductive magnet.

In spite of the fact that MRI is a remarkable new technology with tremendous impact, it is not the imaging panacea. The *sensitivity* is unparalleled compared with any other imaging method; however, the trade-off is that it lacks *specificity* in many disease processes. In this regard, therefore, CT remains the first line investigation in most clinical situations. Other positive features of MRI include excellent multiplanar anatomical detail, the ability to assess tissue characteristics and the fact that it is non-invasive.

On the negative side are the lack of bone detail, slow throughput with examination times averaging about one hour, and patient claustrophobia. The powerful magnetic field plays havoc with pacemakers, video equipment, watches and credit cards. It is also necessary to monitor ferrous materials both in the environment and the patient. Due to the long examination time, it is not acceptable in examining systems subject to motion, e.g. chest and abdomen. In this regard, patient co-operation is also very important.

New advances in MRI include three dimensional imaging, MR angiography and significant decrease in scan times.

The applications of MRI are found predominantly in neuroimaging but also exist in musculoskeletal, cardiac and, to some extent, abdominal systems.

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Imaging of the brain and spinal cord constitutes about 80% of MRI use at the VG Hospital. It has been particularly useful in establishing a diagnosis of M.S., accurately showing the extent of some brain tumors, and the demonstration of congenital and acquired abnormalities at the cranial cervical junction (an area previously very difficult to assess) has been greatly facilitated. Gadolinium is an intravenous contrast medium which is often useful in assessing tumors. It is particularly useful in the diagnosis of very small acoustic neuromas and pituitary lesions.

MRI has greatly improved the diagnostic accuracy in diseases of the spinal cord. Syringomyelia prior to MRI was very difficult to assess. Demonstration of M.S. and various spinal cord tumors is now possible. MRI has been used sparingly for degenerative disc disease at the Victoria General Hospital because of time constraints and the established accuracy of CT and myelography.

MRI has become an important adjunct in the evaluation of a variety of musculoskeletal disorders. Diseases of the bone marrow, both primary and secondary, can be detected and defined with accuracy. Inflammatory and ischemic disorders can often be identified in advance of changes seen in radiographic or isotope studies. MRI is very sensitive in detecting bone and soft tissue tumors but often lacks the specificity necessary for a definite diagnosis. It is superior in defining the extent and anatomical relationships of tumors.

Precise depiction of articular structures by MRI allows accurate assessment of joint disease with particular application in the knees, shoulder, wrist, temporomandibular and sacroiliac joints.

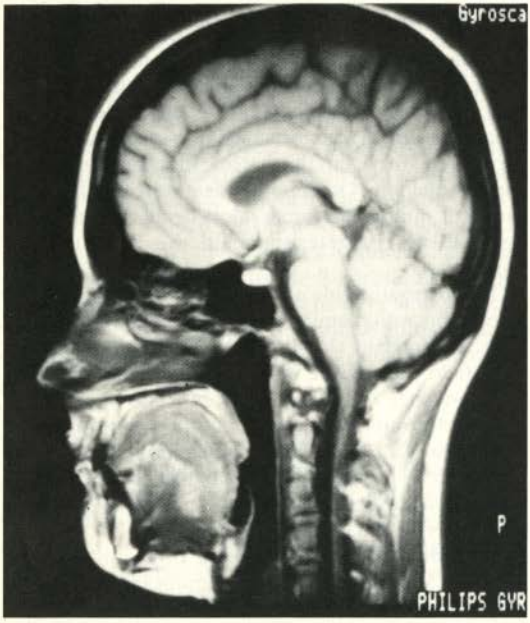

Figure 2

Midline sagittal T-1 weighted MR image of the head.

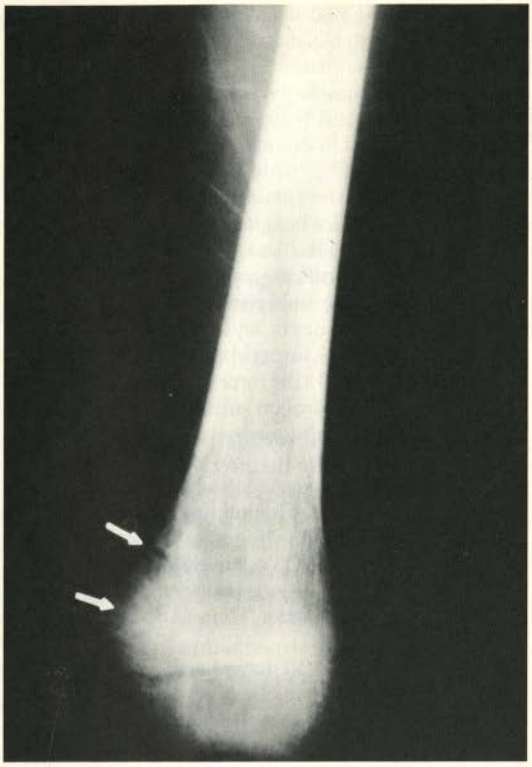

Figure 3

Frontal radiograph of the distal femur demonstrates an ill defined sclerotic lesion with destruction of the medial cortex (arrows).

The role of MRI in cardiac imaging is well defined though somewhat limited. It includes mapping major vessels of the mediastinum in complex congenital heart disease, evaluating invasion and extension of cardiac tumors and both pre and post operative assessment of aortic aneurysms. In ischemic heart disease, myocardial mass, volume and ejection fraction can be measured.

Differentiation between viable and nonviable ischemic muscle is not possible at this time although ongoing research is leading to new developments which may make this a reality. Cardiac MRI investigation constitutes about 2% of the total volume at the VGH.

MRI of the abdomen is still, for the most part, in the early stage of development. Current use mainly includes situations where investigation by other means are unresolved and attempts are made to better define extent and staging of pelvic masses. The ability to obtain multiplanar images and demonstrate anatomy in additional planes is felt to be of great value in imaging abdominal organ systems. Studies of the abdomen and pelvis make up about 3% of the total.

New technology does not come cheap. As well as large capital costs (purchase and renovations), the operating cost is considerable. The total operating expense at the VG Hospital for MRI is in the order of $600,000 per year.

It is only through the vision and co-operative efforts of the Department of Radiology, Victoria General Hospital Administration, Medical Staff, Foundation and Government of Nova Scotia that this state-of-the-art technology exists at the VGH contributing to the excellence of health care for the people of Nova Scotia and other Atlantic Provinces.

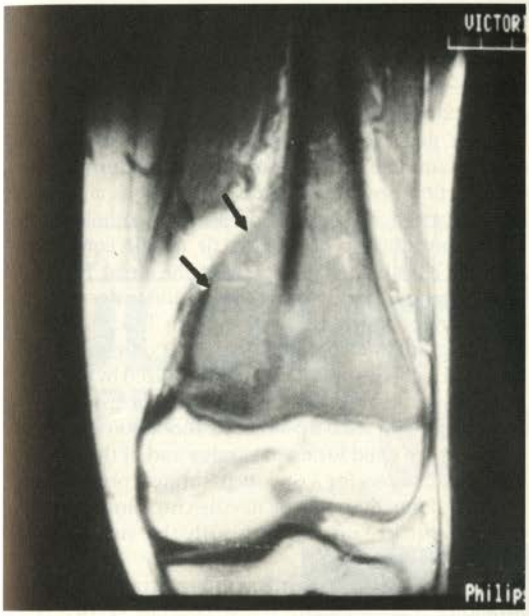

Figure 4

Coronal T1 weighted. Image of the distal femur reveals tumor replacing the medullary canal and limited distally by the growth plate. Soft tissue extension of the neoplasm is noted medially (arrows).

Upon reaching the top of the ladder, you may find it leaning against the wrong wall.

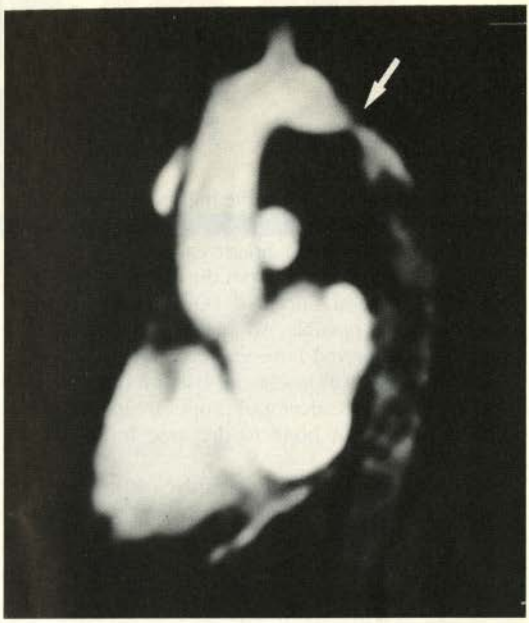

Figure 5

Gradient echo image showing flowing blood. Arrow points to coarctation in the proximal descending aorta. The darker blood in the aorta beyond the arrow is due to an increase in flow velocity caused by the coarctation. □

DIAGNOSTIC ULTRASOUND: CLINICAL APPLICATION

Continued from page 128.

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Nova Scotia – Mammography in the 90s

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Nova Scotian women have the highest mortality from breast cancer in Canada. In the next year, approximately 550 women will develop breast cancer and approximately 200 women will die from the disease.[1]

The cause of breast cancer is not known so that primary prevention is not possible. Advances in all modalities of therapy have achieved little improvement in mortality figures over the past 30 to 40 years. It is only through early detection of breast cancer and proper treatment of the disease that we can hope to decrease breast cancer mortality.[2-8]

Mammography is the most sensitive method we now have for detecting breast cancer at its very earliest state. Properly performed and interpreted mammograms can detect carcinoma 2 to 4 years before it is clinically felt. Carcinomas as small as 4-5 mm. in size and even smaller can be detected by mammography.[5,9,10,11]

Many scientific studies have now clearly shown that with regular screening mammography of women over the age of 50 mortality from breast cancer can be reduced by approximately 30%.[5,11-14]

The Nova Scotia Breast Screening Program opened its first clinic June 1991. Its goal and objective is to reduce mortality from breast cancer in Nova Scotia. Our first clinic is a freestanding clinic located at the Halifax Shopping Centre. Women may be self-referred or physician referred. Letters of invitation are sent to all women in the target age group, 50 to 69 years of age, recommending her participation with then a reminder letter every two years to return. Report from the mammogram is sent to the woman as well as to the primary care physician. The Program will become Province wide, is free of charge and is specifically for Nova Scotia women aged 50 to 69 who have not had a mammogram in the past two years, have no present symptoms of breast cancer, and have not had breast implant surgery.

We are following the Guidelines of the National Workshop Group of 1988 for the early detection of breast cancer and offering physical examination by the technologist, two view mammography and information on the teaching of breast self-examination.[2]

As breast screening becomes better accepted, diagnosis of breast disease must become more accurate to avoid excessive surgical procedures. When two view mammography breast screening is carried out 7-14% of women should have a mammographic lesion which requires further evaluation.[15,48,49,50] The more experienced the Radiologist, the lower the rate of abnormal interpretations. For breast screening to be effective, there must be proper work-up of these lesions which should involve the skilled expertise of a multi-disciplinary team beginning with the Radiologist, Pathologist and Surgeon.[28,29]

Two dedicated work-up centres are associated with the first breast screening clinic incorporating this multidisciplinary team approach.

At the dedicated work-up centre the woman may have extra mammographic views, ultrasound procedures, stereotactic procedures, surgical consultations, and if biopsies are carried out consultations with the pathologist.[16-20]

The introduction of stereotactic needle core biopsy (SNCB) is estimated to decrease the need for open surgical biopsy by approximately 1/3 and to decrease the cost of breast biopsy by approximately 1/3.[27] SNCB is a mammographic technique, whereby a core of tissue is removed from the breast precisely localized by the use of mammographic stereotaxis. This core of tissue allows for a histologic analysis, which if the lesion is benign, alleviates the need for open surgery and, if the lesion is malignant, allows for a one stage surgical procedure to be carried out. Stereotactic needle core biopsy must be carried out in consultation with the surgeon and pathologist.

The Nova Scotia Breast Screening Program strongly promotes a high quality mammography service combined with a team approach to diagnosis. While the benefits to individuals who attend the Nova Scotia Breast Screening Program will not change, tangible benefits of decreased mortality from breast cancer requires the full cooperation and endorsement by the family physician as well as compliance by women in the target age group.[43,45] We must see at least 60-70% of the women in the target age group before we can hope to see a significant decrease in breast cancer mortality in Nova Scotia.

UNDER UTILIZATION OF MAMMOGRAPHY

Surveys of women consistently provide us with two basic explanations for why women have not been screened for breast carcinoma with mammography. They were not aware that they needed the mammogram; or their doctor had not told them to get one.[21-26]

Physicians do not recommend screening mammography for various reasons.[37,39,42,43,46] First, and rightly so, physicians are confused by the various guidelines for mammography and as a result do not participate at all.

GUIDELINES FOR MAMMOGRAPHY

All consensus groups now clearly recommend screening mammography for asymptomatic women over 50 years of age, although there continues to be controversy over the cost effectiveness and cost benefits of screening women under 50 and over 70 years of age.

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All consensus groups agree that symptomatic women, no matter what the age, need diagnostic mammography. In addition women with a strong family history, particularly if it is a sister or mother developed premenopausally, should begin screening at an earlier age.[5,30-33]

RADIATION CONCERNS

Concerns over radiation exposure by both women and physician continue to be a deterrent to mammography as well. However, with the advances in equipment, film screen combination and dedicated processing of films, even the most severe critic of mammography no longer expresses concern about radiation level. The relative risk of a mammogram is equivalent to traveling 70 miles in an airplane or 10 miles by car.[37-41,44,46]

NOT COST EFFECTIVE

Many physicians feel screening for breast cancer is not cost effective. While it is difficult to draw firm conclusions about true cost effectiveness of screening for breast cancer, one can compare this investment with other investments competing for health care dollars. For example, it is estimated that with breast screening, the cost per year of life saved is approximately $20,000 to $50,000. Compared with coronary artery bypass graft of $62,900 per year of life saved and liver transplantation of $225,000 per year of life saved or the use of new low osmolar contrast agents which is $288,000 per year of life saved, the cost of screening for breast cancer is within the generally accepted range of societal investments.[34-37,46]

HIGH NUMBER FALSE POSITIVES

Finally, physicians have been, and perhaps in some areas still are skeptical about mammography. They say there are too many false positives which result in increased anxiety and certainly an unnecessary cost to the medical system. Patients can be assured that regular use of screening mammography may result in saving, not losing, a breast by detecting cancer at a stage when it can be treated conservatively. It is true that breast biopsy is the most common procedure carried out by general surgeons and the vast majority of these, whether carried out on clinical grounds or on mammographic grounds, are benign.[41,43] The adoption of stereotactic needle core biopsy has decreased the need for open biopsy in the work-up centers associated with the Nova Scotia Breast Screening Program.

RESULTS OF THE NOVA SCOTIA BREAST SCREENING PROGRAM FIRST 6 MONTHS

No. of mammograms performed	1900	
No. of work-ups	220	(12%) (standard 7-14%)
Total No. of surgical biopsies	46	
Total No. of malignancies	17	(37% malignant) (Standard 20-40%)
Surgery after core biopsy	19	
benign – 7		
malignant – 12 (60% malignant)		
Surgery no core biopsy	27	
benign – 22		
malignant – 5 (19% malignant)		
Detection rate of cancer	8.9 cancers/1000 exams (standard 6-7/1000 exams)	

Early results from the N.S. Breast Screening are well within accepted standards.[47,15]

Several studies show that a recommendation by a physician is the most compelling reason for a women to have a mammogram.[43,45] Thus Nova Scotia physicians can play an important role in the success of this program and in turn, effecting a decrease in mortality from breast cancer in Nova Scotia. □

References available from author.

Nuclear Medicine Update

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The clinical specialty of nuclear medicine began in the mid 1950s with the production of radionuclides suitable for medical diagnosis from a reactor at Oak Ridge National Laboratories in the USA.[1] In less than 40 years, the use of radioisotopes for diagnosis and treatment of disease has grown from use in a few dedicated research centres to almost every general hospital in the developed world. In this review we will touch on some of the current applications, controversies, and future developments in the field.

One of the first widespread applications of radioisotopes in medicine was the diagnostic use of radioiodine for thyroid disease.[1] The combination of Iodine-131 for uptake measurements and Technetium 99m pertechnetate for scans is used in most centres because ^{123}I, the preferred isotope, is expensive and not readily available. The uptake and scan are most helpful in the differential diagnosis of thyrotoxicosis, readily differentiating Grave's disease, toxic nodular goitre and subacute thyroiditis. With the widespread availability of biochemical measurement of thyroid function, particularly the sensitive T.S.H. assay, nuclear medicine techniques play little role in the diagnosis of hypothyroidism.

The evaluation of thyroid nodules has changed as well. Fine Needle Aspiration Biopsy (FNAB) is now the procedure of choice for most solitary nodules due to its high negative predictive value.[2] Scintigraphy continues to play a role particularly when FNAB is not available, not successful, or not performed due to tumour size or other consideration. A *hot* nodule has a very low probability (less than 2 to 4%) of containing a malignancy compared to 20 to 30% when the nodule is cold.[3] Unfortunately hot nodules occur in only 10% of cases resulting in a low diagnostic yield. Thallium-201 scintigraphy shows promise as a more specific agent for tumour tissue and may well play a greater role in the future.[4,5]

Therapy of Grave's disease with I-131 has been performed since the 1940s and continues to be the most common therapeutic use of open source radioisotopes for non malignant disease. As radioiodine is safe and effective, it has become the preferred therapy for Grave's disease in the United States.[6]

Skeletal scintigraphy is probably the most utilized of all nuclear medicine studies. The high sensitivity of scintigraphy is due to the high affinity of the ^{99m}Tc-labelled diphosphonates for new bone crystal. Bone scintigraphy's greatest impact has been in the evaluation of bone metastases. Studies show that pain,[7] radiography[8] and serum alkaline phosphatase[9] are less sensitive than scintigraphy for metastatic disease. It is important to remember that false negative results may occur particularly in very destructive lesions and lesions that infiltrate or replace marrow. Examples include multiple myeloma, leukaemia, lymphoma, histiocytosis X and some lytic metastatic lesions of breast, melanoma and lung. The timing of follow up studies in patients with known bony metastatic disease is important. Initiation of hormonal therapy or chemotherapy has been shown to cause an increase in both the intensity and number of lesions in patients with metastatic bone disease. This is known as the "flare phenomenon" and is a reflection of improved bone repair in response to successful therapy.[10] This flare may occur up to 6 months or more after the onset of therapy, hence it is advised not to repeat bone scans any less than 6 to 9 months apart. For prostate carcinoma, the prostate specific antigen (PSA) assay is now the study of choice for following patients who are not on hormone treatment and who have had a negative baseline scan. PSA is not specific for bone involvement; therefore scintigraphy continues to play an important role in determining if an elevated PSA is due to bone disease or soft tissue extension of tumour.[11]

Skeletal scintigraphy also has many applications in benign disease. The detection of radiographically occult fractures, particularly stress fractures and insufficiency fractures is an important example. Uptake is usually present on scans performed less than 24 hours after the trama but the scan may take 3 or more days to become positive in elderly patients.[12] Scintigraphy for infection, particularly haematogenous osteomyelitis, is very sensitive, but specificity is poor when there is underlying bone pathology such as fracture, internal hardware, or in the diabetic foot. The addition of infection imaging agents improves specificity.

Labelled leucocyte studies are useful in delineating sites of infection and inflammation. The work-up of abdominal sepsis, inflammatory bowel disease and skeletal infection are all major indications for labelled leucocytes. The technique does however have pitfalls. Leucocyte imaging is sensitive for detection of infection of total hip prosthesis but its specificity may be compromised by the presence of active marrow in unusual sites. The addition of technetium sulphur colloid bone marrow imaging to map the distribution of bone marrow improves the specificity greatly; hence this combination is now recommended.[13] One site where leucocyte imaging is not recommended is in the spine where the sensitivity for infection has been reported as low as 17%.[14] Although leucocyte imaging has clear advantages in many situations, it is not widely performed due to its relative expense and technical demands. This may change in the

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future as agents are being developed to label leucocytes in vivo and other agents such as labelled polyclonal IgGs are being studied as possible replacements to labelled leucocytes.

Gallium citrate is the other widely used agent for inflammation imaging. For the majority of infections, labelled leucocytes are the agent of choice, but gallium is still preferred in chronic infections, discitis, sarcoid, inflammatory lung disease and pneumocystis carinii infections. The value of gallium as a tumour seeking agent makes it a very valuable test in patients with fever of unknown origin.

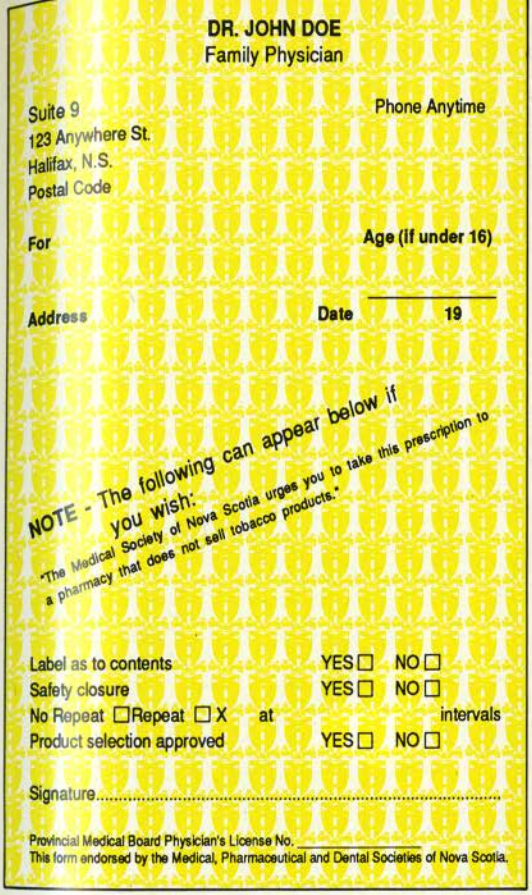
The detection of neoplasia is the focus of research in many disciplines. Gallium citrate has been used in a number of malignancies, most notably the lymphomas. The accuracy of gallium in the lymphomas was originally found only to be fair, but recent studies with high dose gallium, delayed imaging and tomographic technique have shown it to be an excellent marker of tumour viability in the lymphomas.[15-19] Thallium-201, the myocardial agent, has also been studied widely as an imaging agent in lymphomas, lung cancer, breast cancer, thyroid cancer and brain metastasis.[5,20-25] Specific tumour agents from monoclonal antibodies continue to be the subject of research worldwide. Unfortunately the development of these "magic bullets" has been disappointing. There are many difficulties in development including problems producing antibodies that are both highly sensitive and highly specific and obtaining high absolute delivery of tracer to the lesion.[26] Despite these problems, labelled monoclonal antibodies will almost certainly play a role in diagnosis in the future.

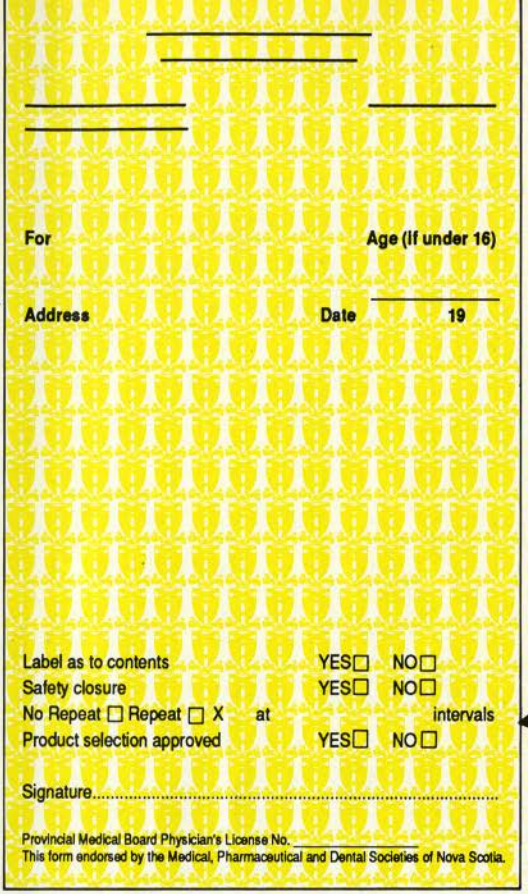
There are a wide variety of nuclear medicine studies of the G.I. tract . The liver spleen scan is no longer frequently performed due to the availability of ultrasound and computed tomography. Gastrointestinal bleeding studies with tagged RBCs are highly sensitive in the detection of GI tract bleeding.[27] The key to this study is that the patient must be actively bleeding at the time the study is performed hence all efforts must be made to study the patient as soon as acute bleeding is suspected. Hepatic haemangiomas are a very common incidental finding in ultrasound examinations done for some other indication and it is frequently important to differentiate these lesions from metastatic deposits. Tagged R.B.C. blood pool studies, particularly when combined with tomographic imaging, are sensitive and almost 100% specific for haemangiomas when they are at least 1.5 cm in size.[28-30] Hepatobiliary scintigraphy (HIDA) is helpful in a number of biliary tract problems but the most common indication is in the evaluation of acute cholecystitis. Sensitivity and specificity are greater than 95% in ambulatory patients;[31-34] however false positive studies may occur in very ill patients due to prolonged fasting and the use of total parenteral nutrition.[32] The use of morphine at 40 or 60 minutes to contract the sphincter of Oddi and hasten filling of the gall bladder can shorten examination time.[33] In addition the use of Sincalide (cholecystokinin-8) to empty a hypotonic gall bladder prior to the exam may improve its specificity.[35] The Carbon-14 urea breath test, a relatively new study, is being employed in the diagnosis of gastritis caused by *Helicobacter pylori*. In this examination C-14 labelled urea is swallowed, metabolized in the stomach by the bacteria and is detected in the breath as C-14 CO_2. This is a very accurate tool but is not yet in widespread clinical use.[36]

Renal scintigraphy is currently performed with one of a number of radiopharmaceuticals including ^{99m}Tc-DTPA, ^{99m}Tc-Glucoheptonate, ^{99m}Tc-DMSA, and ^{131}I-hippuran. Each finds its niche in renal function evaluation. An interesting new application of renal scintigraphy in the evaluation of renal hypertension. In patients with renal artery stenosis, angiotensin converting enzyme inhibitors (A.C.E.I.) eg. captopril, will cause a decrease in tone of the efferent glomerular arteriole causing a decrease in perfusion pressure of the glomerulus and a fall in G.F.R. This change can be detected on renal scintigraphy therefore it is a promising tool in the evaluation of renovascular hypertension.[37] Another development is the introduction of a new radiopharmaceutical ^{99m}Tc-MAG_3 which has all the benefits of both the commonly used tracers (^{99m}Tc-DTPA and ^{131}I-hippurate) without their major disadvantages.[38] Unfortunately, like many new pharmaceuticals, it is relatively expensive and this may impede its introduction into routine use.

Lung scanning is the preferred first imaging test for the evaluation of possible pulmonary embolism. Since the retrospective studies of Biello and others, most centres now report lung scans using a probability scale; normal: essentially no probability of embolism; low probability: most likely no pulmonary embolism (approximately 15% probability); indeterminate probability: ie. equivocal (30 - 50% probability); and high probability: most likely pulmonary embolism (greater than 85% probability).[39] Prospective studies by Hull and particularly the multicentre PIOPED study, have confirmed that these are reasonable estimates of probability. Hull stressed that pulmonary embolism is part of the spectrum of thromboembolic disease and evaluation for the presence of peripheral thrombus can have a great impact on risk stratification in patients suspected of having pulmonary emboli. PIOPED emphasized the importance of pretest probability in the likelihood of pulmonary embolism post lung scan. The interested reader is referred to a number of articles listed in the bibliography.[40-46]

The noninvasive investigation of cardiac disease has grown considerably in recent years. Gated blood pool studies, also known as wall motion studies, RVGs or MUGA scans continue to be a reliable, simple and reproducible method of evaluation of ventricular function. Myocardial perfusion studies (thallium scans) have a good overall sensitivity (85%) and specificity (85%) but results vary from institution to institution.[47,48] Recent interest has surrounded the issue of myocardial viability post infarction. In stress thallium studies, images are obtained immediately after stress and again after a 3 hour delay. Defects that improve (reverse) after the delay are said to be representative of provocable ischemia and





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those that do not, representative of infarction. However, numerous investigators have shown that by either performing the delayed study after a 24 hour wait or by performing a second study at rest, non reversible lesions frequently show improvement in thallium uptake indicating that viable myocardium exists in that region.[49]

^{99m}Tc sestamibi, a new myocardial perfusion agent, has certain technical advantages over thallium but has not been shown to more accurate in the diagnosis of ischemia and may be limited by the need for a two day protocol and lack of sensitivity for viable myocardium. Thallium, therefore, continues to be the preferred agent in our laboratory. Numerous other agents are currently the topic of research including agents that reflect metabolism and not simply perfusion.

The brain scan, once the most common study in Nuclear Medicine departments, has now all but been replaced by computed tomography and MRI. In areas where CT exists, the conventional brain scan has only two good indications, the evaluation of brain death and the early evaluation of encephalitis. Brain scanning is however approximately 90% sensitive overall and is therefore still a valuable tool in regions where CT is not available. Brain perfusion imaging with ^{99m}Tc hexamethylpropyleneamine oxime, HMPAO, is now being used in the differential diagnosis of depression and dementia in the elderly and in the early diagnosis of stroke.[50-52] New high resolution multiheaded tomography cameras are now producing images approaching the resolution of P.E.T. and investigators are now finding perfusion imaging a useful tool in other diseases as well. As such state of the art equipment is expensive we may not see installation of multi headed equipment in Nova Scotia for some time.

Radioisotopes are also extensively used for therapy as well as diagnosis. ^{131}I therapy for thyroid ablation and recurrent thyroid tumour has been used for decades. Other established therapies include ^{32}P for polycythemia ruba vera and ^{32}P and other colloids for inflammatory arthritis. Many newer therapies are being evaluated clinically including Strontium-89 for painful bone metastasis, intraarterial colloids for liver metastasis, ^{131}I metaiodobenzylguanidine for metastatic pheochromocytoma and various ^{131}I labelled antibodies for a host of malignancies.

As we move toward the twenty first century, the development of new single photon radiopharmaceuticals tailored to probe metabolism will provide exciting insights into the workings of the human body in health and disease. □

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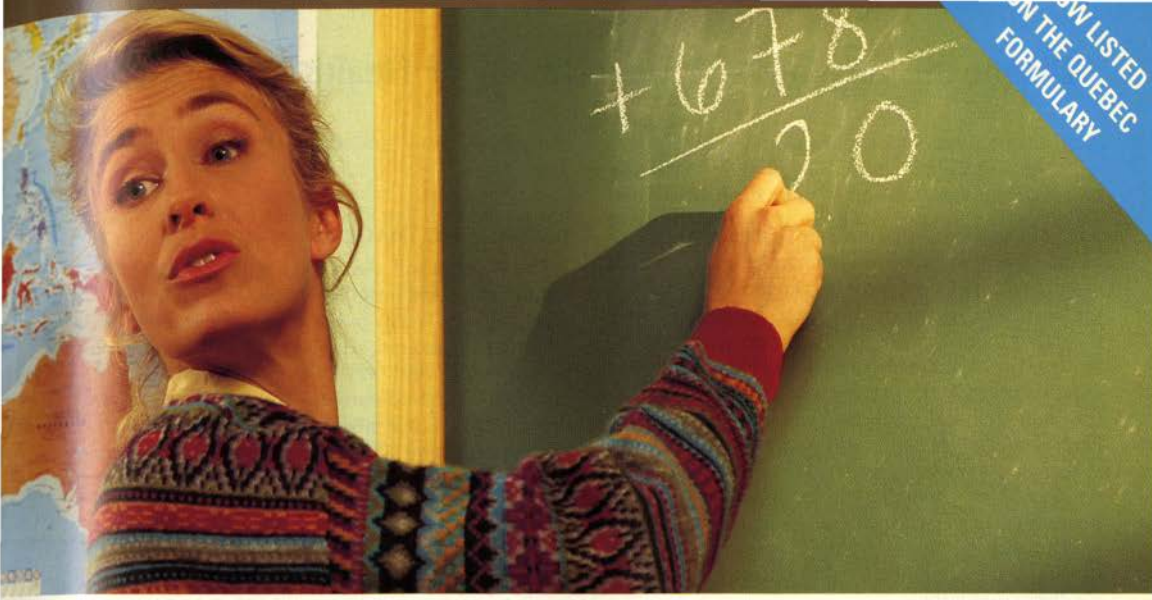

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Diagnostic Imaging – A Department of Health Perspective

John Malcom*

Halifax, N.S.

It is not news to you that these are challenging times for health care. Nova Scotia is not immune to the demands of an aging population, and Nova Scotians wish to receive the benefits of proven advances in technology. To meet these challenges in an era of restrained economic growth requires the commitment of all health care providers to examine critically the present use of our financial, human and technical resources. The next few years are likely to be a time of significant change in our health care system as we strive to serve more effectively the needs of the population without significant growth in health expenditures. The Department of Health is committed to working with the public and health care providers as we develop new mechanisms to address these challenges in a collaborative fashion.

THE ECONOMIC BACKGROUND

Canadians have chosen to fund health care services primarily from government revenues in order to assure all residents of access to universal health care. A starting point on any discussion of the future direction of our health care system must therefore include a financial statement on the "health" of governments financial position. A few key facts in this area are;

- Nova Scotia presently runs an operating deficit (projected at $346 million in 1991/92) and has run deficits for a number of years.
- The provincial debt of $4.8 billion means each Nova Scotian owes $5,400.
- 18% of government spending must go to service this debt.
- Health represents the largest single government expenditure ($1.3 billion, 28% of government expenditures, or $1,525 per person).
- The rate of growth in provincial health expenditure over the past 10 years has averaged 8.8% per year which has exceeded both the growth rate in inflation (5.1%) and revenues (7.5%).
- The Province has adopted a three year spending increase target of 0% in 1992-93, 0% in 1993-94 and 3% in 1994-95 in order to reach a balanced budget.

DIAGNOSTIC IMAGING

The Province will spend $58.8 million in 1992/93 to support diagnostic imaging services. This amount covers all health care facility based charges for X-ray, nuclear medicine, ultrasound, CT Scans and M.R. services. Our projections for 1991/92 are that Nova Scotia health care facilities will provide around 900,000 X-ray examinations, 52,000 nuclear medicine examinations, 31,000 CT examinations, and 100,000 ultrasound examinations, or an average of 1.2 examinations per person. Over the past five years the total rate of examinations in X-ray and in nuclear medicine has changed only marginally. Over the past three years the number of CT examinations has also been stable. The area of growth has been in ultrasound which has risen by approximately 17% from 1987/88 to 1991/92. (Fig. 1)

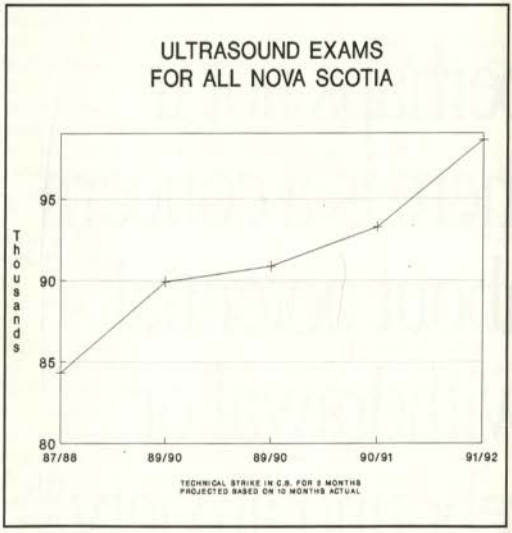

Fig. 1

While these figures on their own are interesting their real value, is seen by examining utilization in light of the population served. Figures 2, 3 and 4 attempt to identify rates per 1,000 population for X-ray, nuclear medicine and ultrasound on the basis of the six planning regions adopted by the Department of Health. As a response to the Royal Commission Report, the Department has adopted the following regional boundaries:

- South Western Nova Scotia includes the counties of Lunenburg, Queens, Shelburne, Yarmouth and Digby.
- Valley includes the counties of Annapolis, Kings and West Hants.

*Administrator, Health Care Facilities, Department of Health, Province of Nova Scotia.

- Halifax includes Halifax County and East Hants, excluding the Noel Shore area.
- Cobequid includes Colchester and Cumberland Counties and Noel Shore.
- Northumberland includes Pictou, Antigonish and Guysborough counties.
- Cape Breton includes Inverness, Victoria, Richmond and Cape Breton counties.

It should be noted that these are gross rates per 1,000 population that have not been age standardized. Also our collection of data does not identify place of residence, so referred-in work will be counted within the volume of the receiving hospital against the local population. This would help to explain the higher than average rates for residents of Halifax for example. Even with these imperfections there is benefit in examining this data to attempt to understand the reasons behind these variations and to ask the question posed by Dr. John Wennburg of Dartmouth University, "Which rate is right?"

Answers to questions such as;

Why do residents of Cape Breton have the highest rate of X-ray examinations per thousand? Why do residents of Northumberland have the highest rate of ultrasound examinations?

How do you explain the variations in the rate of nuclear medicine examinations between regions?

The Department is anxious to examine these issues collaboratively with Nova Scotia Radiologists to better understand the reasons behind the small area variations represented by these graphs and to confirm the appropriateness of the resources allocation decisions inherent with this information.

In addition to examining issues surrounding the utilization of health services, it is essential that all health care professionals examine ways of more effectively delivering these services.

Over the past year, staff of the Department and the Executive of Nova Scotia Radiologists have worked to reduce expenditures on contrast media. In addition to examining ways of obtaining improved pricing for products and to reduce wastage, discussions have also centred on recent research finding in order to better understand factors behind the appropriate use of low verus high osmolar contrast media. Overall reductions of approximately 30% or $650,000 were achieved in 1991/92 when compared with the 1990-91 expenditure levels in hospitals.

REGIONAL PLANNING

As was already referenced, the Department has adopted six planning regions in response to the Royal Commission Report. These will form the basis of local and

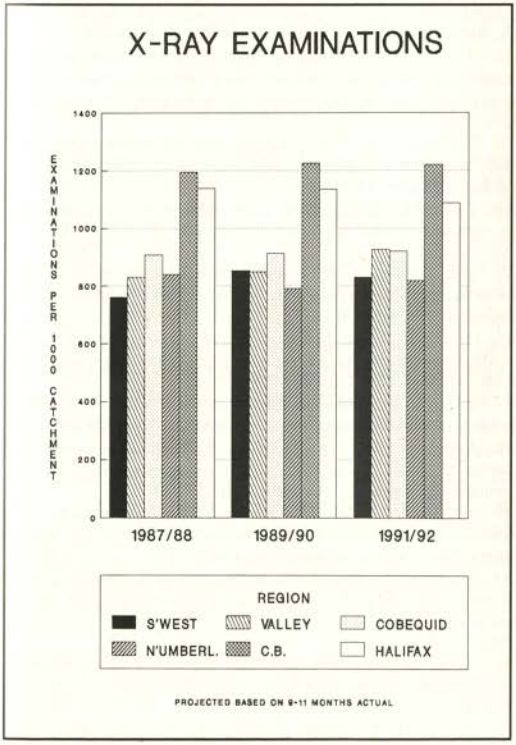

Fig. 2

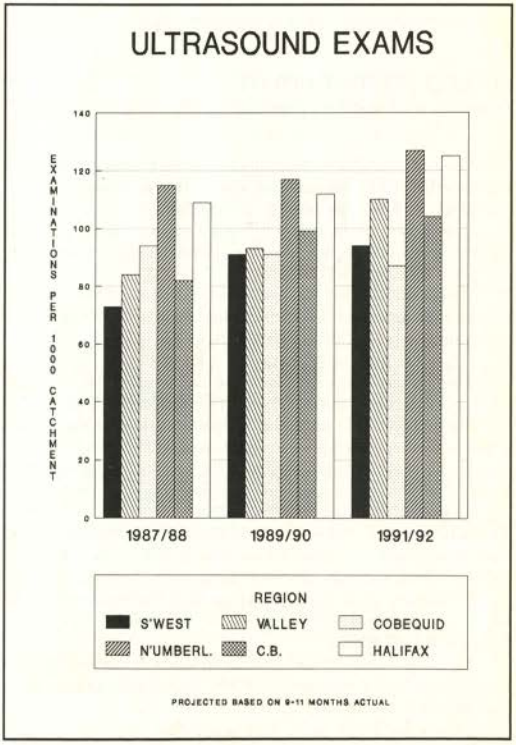

Fig. 3

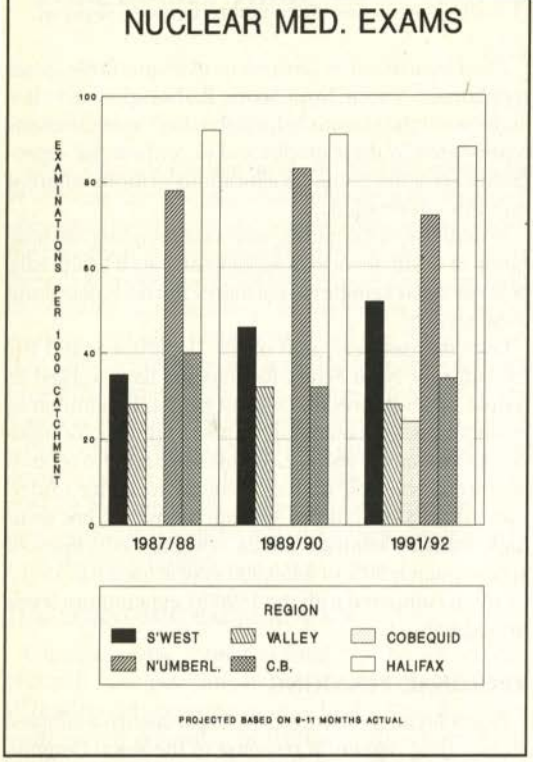

Fig.4

tic imaging all regions presently offer X-ray, ultrasound and nuclear medicine services. By the end of 1992/93 all regions will also be able to offer CT scanning at a facility within their region. This will complete the provincial plan for dissemination of CT scanning over the next few years. The Department will shift its priority to completion of a province-wide mammography screening system for women between the ages of 50-69. At present there are no plans to expand the number of sites providing M.R. services.

While this article started with reference to the challenges facing our health care system, it seems only appropriate to end it on a note of optimism. There is much to be optimistic about and we can take pride in the accomplishments to date. The Department of Health is committed to working with health care professionals and the public to ensure that the benefits of our present system are maintained while striving to redirect our efforts to those areas that will have most benefit on improving the health status of Nova Scotians. □

NUCLEAR MEDICINE UPDATE

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Standards in Medicine – The Radiology Perspective

WE'VE ONLY JUST BEGUN

G.J. Butler,* MD, FRCPC

Kentville, N.S.

The movement towards greater medical accountability is both inevitable and underway. The increasing interest in producing written standards and a method of insuring general adherence to them could be seen by us as a golden opportunity to describe the jobs we do, point with pride to the quality of our work, and lead the way towards a constructive program for maintaining our own proficiency.

In May 1991, the groundwork was laid for a program of Peer Review in Atlantic Canada, administered jointly by the Provincial Licensing Authorities and the Medical Societies of the Atlantic Provinces. Legislation enabling this process has already been enacted in New Brunswick and is apparently in the works in Nova Scotia. Further impetus for government encouraged programs may come in fact from adoption of the Barer-Stoddard Report by the nation's ministers of health in January of 1992. This report may have lasting impact on matters of fundamental importance to us as a profession.

Within our own Medical Society, the Section of Anaesthesia commenced its own voluntary peer review process a few years ago. This has received financial backing from the Department of Health and has proven largely to be well received by the province's anaesthetists.

The Royal College has instituted a Maintenance of Competence Program which is under pilot study by most divisions this year.

In radiology, plans have been started to commence our own peer review program in Nova Scotia. This would be administered by the Section of Radiology (NSAR) and will be based in part on the Anaesthesia[10] model. While many physicians may initially view the matter of standards and review as an intrusion on their professional freedom, it is true that hospital accreditation organizations, administrators, and government agencies have increasingly asked for proof of practice quality, appropriateness of utilization and optimization of outcome. It would seem our opportunity and responsibility to lead in this process, rather than wait to be led by non physicians.

Standards of training and practice are being simultaneously drafted by the American College of Radiology and the Canadian Association of Radiologists. Standard is defined by the American College as a statement about who is qualified to perform diagnostic and therapeutic procedures; what information is desired from these procedures; and what to do with that information. Quality assurance, soon to be known as quality improvement, would involve some method of monitoring and evaluation. For radiology, this might include:

- Accuracy of interpretation
- Technical success rates and complication for invasive procedures
- Radiation safety in diagnosis, nuclear medicine and radiotherapy
- Quality control procedures for the radiology department
- Documentation (images and reports)
- Appropriate communication with referring physicians and patients
- Coverage during and after hours for all needed examinations
- Handling of acutely ill patients
- Evaluating the appropriateness of an examination based upon the clinical information provided on imaging examination requests
- Outcome studies which would attempt to quantify impact on mortality, morbidity and quality of life.[1,3]

Additional items for review might include:

- Technologist performance
- Practitioner quality of life and longevity
- Administrative performance
- Continuing Education and upgrading of skills

This is a formidable list. Expectation cannot be set at unrealistic or unattainable levels. By far and away the approach most likely to succeed is one which would promote continuous improvement rather than identification per se of shortcomings. Active rather than passive participation would be encouraged by emphasis on the positive goals and the constructive, non punitive nature of the process. We will be craving feedback from both within and without our section during our commencement of our own standards projects. We encourage and support other Sections to do the same.

The 1990s are bringing with them funding difficulties, higher taxes and a move towards medical standards programs. May the latter become a positive feature of the decade. □

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BAS

Dr. Harold E. Killam
A Country Physician at the Turn of the Twentieth Century
FIRST YEARS 1906-1918

Kathleen (Killam) Cogswell

Berwick, N.S.

What was it like to be a medical doctor in rural Nova Scotia at the turn of the twentieth century? My father was such a man and I shall try to tell a little of what it was like for him.

Dr. Harold Killam had never intended to set up practice in Woodville, Kings County – the little village in which he had been born in 1878 – but when he stepped off the train at Cambridge Station after his graduation from Dalhousie University in the spring of 1906, he was met by a delegation of local people urging him to stay and promising to employ him. Flattered and touched by their faith in him, he agreed to try it for a year. He stayed all his life.

So what was it like?

First he had to set up an office and he had no money. What little he had been able to save after a few years of teaching at the pitifully small salaries then paid and from working later at a chair factory in New Hampshire, had all gone for his education. He might not have managed college expenses at all if his older brother, Fred, employed at and later owner of Nova Scotia Nurseries, had not given him free room and board.

Accommodations at one of the college-approved boarding houses – there were no college residences then – would have cost him twelve to fifteen dollars a month, a small sum to us nearly nine decades later but a substantial amount at that time when a labourer often worked a ten-hour day for fifty cents. Harold Killam's little store of money was needed to pay college fees: $2.00 for registration, AND $15.00 or less* for each of the six or seven courses required in each of the four years's study then leading to the coveted degree.

EDITOR'S NOTE

Readers of *The Journal* will find this article of historical interest. It was originally written for family members.

Mrs. Cogswell states that her only claim to fame is that she is the daughter, widow, mother, and mother-in-law of physicians, all of whom graduated from Dalhousie.

Father: Dr. H.E. Killam
Husband: Dr. L.E. Cogswell
Sons: Dr. David Cogswell, Aylesford, N.S.;
Dr. Eric E. Cogswell, Burlington, Ontario
Son-in-law: Dr. Graham Pineo, Calgary, Alberta

Mrs. Cogswell is also a graduate of Dalhousie (Arts, 1930).

Although H.E. Killam is listed as a first year student at Halifax Medical College in 1902, he graduated four years later from Dalhousie University, the college having become the Faculty of Medicine for the university in 1885. While the school did most of the teaching, the university presented the degrees. Twenty men and one woman are listed in the 1903-1904 Medical College calendar as having begun first year studies in 1902 but only thirteen of the men and the one woman are listed as having passed the examinations at the end of that term. The pass mark at that time was only 50% but maybe the examiners were tough? (Would **you** like to employ a doctor who only half knew his profession?)

While no pre-med classes were then required for entrance to the college, all candidates had to pass matriculation examinations set and marked by the Provincial Medical Board. Included in the list of compulsory subjects were Latin and one foreign language. That posed a problem for my father, who had received his early education in a country school where such subjects were not taught.

**Practical Anatomy,* for example, was only $5.00

School teachers at that time, and even much later, often had very little education themselves. They needed only to have passed provincial examinations in one of the high school grades 9, 10, 11, or 12 and to have written successfully MPQ (Minimum Professional Requirements) examinations to be awarded a permissive licence to teach. H.K. himself took advantage of that opportunity after he passed grade 11, and began teaching in a one-room school 'over the mountain' when he was only sixteen. Later he attended Normal School in Truro to upgrade his licence to a 'B' level. But he really did not want to teach school all his life, so after a few years he did what so many of his contemporaries did; he went to "The Boston States" to seek employment at higher wages. In Greenville, New Hampshire, he found a job in a chair factory and a private tutor in the town to teach him Latin and German.

Matriculation over, he settled down to four years of study at the Halifax Medical College, with clinical instruction given at the Victoria General Hospital and in the Lying-in (Maternity) and Hospital wards of the city Alms House, etc. Conditions at the school were described by Dr. Kenneth MacKenzie, who graduated in 1903:

> "The wooden operating table was still in use. No rubber gloves were used. Sponges were the commercial sea sponges which were sterilized and used over and over again. The complicated methods of sterilizing the hands in some cases caused a dermatitis which forced some surgeons to abandon surgery. The only private rooms in Halifax were five in the Victoria General Hospital and thirty in the Halifax Infirmary. Surgery was often done in the homes – kitchen surgery. Laboratory work in the Victoria General was done by the senior students and internes and included blood counts, urinary sediments and parasites. Chemical tests for albumin, sugar and blood in stools were routine. Sputum was examined for tubercle bacilli and other organisms. Anaesthetics were administered by senior students and internes. Ether and chloroform by the open method. There were no specialists in anaesthesia."

Practice in surgical operations were given 'on the dead body'.

With his graduation from Dalhousie in 1906, Killam's formal education was over. He now had the degree of M.D., C.M. (Medical Doctor, Master of Surgery). He had been licensed by the Provincial Medical Board. He had been invited to set up practice in Woodville. But he had no money.

What now?

Since the first year was to be a trial period there was no need to make permanent arrangements immediately. Fortunately he had a very supportive family. A younger brother, Percy, who now owned the family home*, invited him to move in with him and their two unmarried sisters. A small room with an outside entrance was set aside as an office. For the time being the dining room would have to double as a waiting room. On fine days his patients liked to hitch their horses in the yard and visit with each other anyway while they waited to be called. There were no office hours. Patients were seen any time the doctor was home.

His older sister, Winifred, was his first combined receptionist and housekeeper. She was proud of the brother she had helped to bring up after their mother's death and had a picture taken of him "Waiting for his First Patient." The faded picture shows a young man in a high starched collar sitting stiffly upright in an old-fashioned chair, while above him are open shelves with his store of medicines. Most country doctors of that time dispensed their own medications for the convenience of their patients. Prescriptions were given only for medicines they could not supply. Someone then had a long drive 'in a horse and wagon' to a drugstore in the nearest town.

In 1906 horses still provided most of the transportation in the Valley. The few automobiles of the day were luxuries, the roads being so bad that cars could be used only a few months in the summer.** My father at first could not afford one. A snapshot taken about 1910 shows him seated in his 'rubber-tired buggy' in front of his office door. Hitched to the wagon is his first horse, Gem, the only horse he ever loved. Once he had completed a call he could head 'the little mare', the 'little Frenchman', in the right direction, throw the reins over the dashboard, and know she would take him safely home while he slept – perhaps the only sleep he would get that night. Why wouldn't he love her? He even credited her with saving his life one dark and stormy night when she refused to cross a bridge in spite of a 'cut with the whip' so rarely felt by her. Investigation revealed that the bridge was gone, swept away by the swollen stream.

There were other horses of course. The doctor had to keep two at all times, for his practice covered a wide area, from Hall's Harbour to Harbourville along the Bay of Fundy coast and the width of the valley to the South Mountain and beyond. Often he would get home from a long and tiring trip only to find an urgent call in another direction. So the first horse would be rubbed down, blanketed and fed to get a much needed rest, while the other would be hitched up. Two horses but only one man. He was tired too but he never refused a call.

Doctors today can scarcely credit how much of my father's time was spent on the road. There were no hospitals in the Valley then and no ambulances. Patients too ill to come to the office – and many were very ill before they resorted to the extreme measure of calling the doctor – were seen in their home. Broken bones were set

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* Harold Killam was the eighth child in a family of ten. He was four years old when his mother died giving birth to her tenth baby. Her probably needless death illustrates the problems faced by people of the day when communications were so difficult. No automobiles and, even worse, no telephones. Her husband left her in the care of the local midwife and went for the doctor. But the doctor was not at his home in Lakeville, only three miles away but in Hall's Harbour on the Bay of Fundy, twelve miles further, with a steep mountain road to climb for his weary horse. It was some hours later that he got back to find his son born and his wife dead from hemorrhage. He never married again.

**In 1907 only 59 automobiles were registered in all of Nova Scotia. 11 of them in Kings County. No doctor's names are listed as such.

by skillful hands without benefit of x-rays,* and bad cuts stitched and emergency operations performed on kitchen tables, occasionally with the help of a practical nurse who put the patient to sleep by dropping chloroform on a face mask, but often with just the help of be a family member (who might prove to be more of a hindrance than a help), and sometimes with no help at all.

Serious cases that needed the attention of a specialist were sent to the Victoria General Hospital in Halifax, usually on a stretcher in a baggage car of the Dominion Atlantic Railway, a long, dreary, jolting ride in a dark unheated car. Occasionally, the doctor accompanied a very sick and/or apprehensive patient to the hospital, returning on the next train.

Matters were improved when in 1922 the first hospital in the Valley built **for** a hospital was built in Berwick, eight miles from Woodville. Dr. Killam was one of the founders of that hospital, and his name appears on the charter.**

But that was in the future. In 1906 there was no hospital. It was the day of the house call, and the country roads were incredibly bad, especially in winter and early spring. Taxes were light, but in lieu of higher taxes property owners were required by law to donate a certain number of hours to 'road work' (statute labour).*** Those who could not do the work themselves had to hire men to do it for them. A 'road boss' (a political appointee) would summon the men on certain days to fill in the worst of the pot-holes in spring or to dig through drifts after a snow-storm so that a horse and sleigh could get through. Many times they took down part of a farmer's fence and made a temporary road through his fields to avoid digging through an especially high drift. Somehow babies seemed to prefer being born on stormy winter nights. Helpful neighbours would then enthusiastically dig the doctor through to his patient, but he was usually left to his own devices to find his way home some hours later. All too often the storm had continued and the drifts were even higher.

Dad could tell many a tale about his experiences. For example, one very dark and stormy night he was coming home from a confinement case on the mountain, well bundled up in his buffalo coat and buffalo lap-robe, a warm scarf tied around his neck and fur cap. Gem was slowly picking her way, finding it difficult with the blowing snow erasing all trace of the road, and, as usual under those conditions he was talking to her to give her encouragement. Suddenly a man leaped out of the bushes and levelled a shot-gun at him. "What are you doing here", he demanded, "and where are the others?" "I'm just trying to find my way home, and there are no others," "Well, get out of here quick, and don't come back!" A week or two later he told a patient in the office about the scare he had had near his home. The man burst out laughing. "So that was you!" he said. "Sorry! I thought you were one of a gang of thieves who had been robbing smokehouses in the area – mine, for one – and were driving the get-away team while the others stole the hams. I had decided to give them such a scare that they would not come back."

There was no pavement, no hospital, and no electricity but there were telephones, a great boon to the doctor. Just a year or so before my father set up practice, Thomas Lawson, an enterprising country merchant, had set up a switchboard in his little general store at Buckley's Corner (now Grafton), partly as a convenience for himself. Supplies for the store were often brought by boat to the wharf at Canada Creek from Saint John, New Brunswick. Freight by sea was cheaper than by rail, but less reliable. Sometimes heavy wagons pulled by a team of oxen or draft horses would make their slow way over the mountain only to find that the steamer had not arrived. Time and money could be saved by the telephone both for him and for others.

How very new telephone service was to the area can be seen by the obituary of my grandfather, W.H. Killam, who died in April, 1905. News of his expected death (from pneumonia and pernicious anemia) was sent to his sons in Halifax by telegram from the railway station in Cambridge. Obviously no telephones were in service then.

The Farmers' Telephone Company was a rather informal affair. Father used to chuckle about calling central and having Tommy say, "Wait a but! Wait a but!" as he attended to a customer before connecting the lines. On one occasion after a patient had assured him that the road to his home was "not too bad", Tommy broke in to say, "Don't ye believe him, Doc! That road ain't fit for man nor beast!"

At first the local people were rather skeptical of the new idea. A few of the more progressive had phones installed and the whole community used them. It was cheaper that way. To the thrifty farmer what was the use of having a phone when there were so few people you could call! Better save the $10.00 per year subscription fee and use a neighbour's in an emergency. Quite quickly, however the phone 'caught on'; the number of subscribers grew; and in 1919 the Farmers' Telephone Company was sold to the larger Maritime Tel. & Tel., which had exchanges in Kentville (about ten miles from Woodville) and Berwick (eight miles).

The Killam house happened to be very near the dividing line between the Kentville and Berwick exchanges and the doctor had patients in both areas. He therefore had two telephones, one (Berwick) on the wall in his office and the other (Kentville) on the wall of the dining room just beside the connecting door to the office. In his bedroom he had an extension of the Kentville phone and a bell-box for the Berwick line. If the Berwick bell rang during the night he first checked and if the Kentville line was not busy he threw a switch and received the Berwick call on the Kentville line – a special arrangement for the doctor.

*The first x-ray in the Valley was taken at the Provincial Sanitorium in Kentville, Oct. 21, 1918.

**There was a small cottage hospital in Windsor.

****An Act Relating to Highways*, passed by the Legislature in April, 1907, required all male persons 16 to 60 years of age to pay a poll tax of "never less than $1.00 or more than $2.00" for upkeep of roads. The tax could be commuted by labour, each man to provide his own tools and to be credited by $1.25 for an eight hour day.

All the phones in rural areas were, of course, on party lines. Private lines so far from the telephone offices would have been prohibitively expensive. At a time when there were no radios or TVs the party line was a prime source of information and entertainment. The doctor's ring (a 'long and two shorts' for Berwick and 'two longs and four shorts' for Kentville) was sure to be monitored. "Who's calling the doctor? What's wrong? Who's sick?" That was annoying but sometimes it was useful. A listener, not at all ashamed of having eavesdropped, might break in to say that a certain road was impassible and suggest an alternate if somewhat longer route. Many times it also meant that when the doctor was called to see a patient in, e.g., Hall's Harbour, he would find a number of less ill neighbours asking him to call at their homes too, thus saving themselves the fifteen mile drive to his office or the mileage cost of a special trip to their homes. That saved time for the doctor as well as the patient.

Telephones were wonderful, but there were few other amenities in rural Nova Scotia at the turn of the century. There was no electricity and therefore no labour-saving devices powered by it. When my father began practice there was not even a bathroom in the house, but when his first child, Margaret*, was beginning to creep he had one installed. The water system was an ingenious gravity flow arrangement. In the kitchen in the old ell (later torn off) there was a black cast-iron sink and a hand-pump. A valve in the pump could be closed so that water ceased to flow into the sink and was forced through a small pipe – exposed plumbing – into a lead-lined wooden tank in the attic of the one and a half storey house. When the tank was full, water trickled down a smaller lead pipe into the sink, much to the relief of the hired man whose last job at night was to do the pumping. We children were cautioned not to waste water. Two to a bath was more fun anyway. Since tap water was never used for drinking or cooking, there was little danger of lead poisoning.

Water for the bathroom was heated in the 'hot-water-front' in the wood-fired kitchen stove. That meant that there was plenty of hot water in the winter but not much in the summer when a continuous fire made the house unbearably hot. Sister Margaret enjoyed cold baths. I didn't. Sometimes our mother would heat water on the portable kerosene oil-stove and pour it into the tub to take the chill off.

The doctor sterilized his instruments by boiling them on the kitchen stove or when the fire was out, on the oil-stove. Sometimes he would squirt at us children a fine stream of water from his hypodermic needle – re-usable syringes and needles, of course. In his office he had an alcohol lamp for making urine tests, etc., for he was perforce his own lab technician. For sophisticated tests he had to send specimens to Halifax, a time-consuming procedure. Usually he trusted his own diagnosis and began treatment before receiving the report.

Prompt and accurate diagnosis and early start of treatment were of the utmost importance at that time. There were many common diseases but few with effective remedies. The so-called children's diseases, such as whooping cough, measles, chickenpox, mumps, scarlet fever, etc., still took their toll. Diphtheria was not uncommon although antitoxin was available to ease its severity. But there was no effective remedy for another dreaded enemy, infantile paralysis, and parents and doctors alike breathed easier whenever the 'polio season' (late summer and early fall) passed without an outbreak of the disease.

Afflicting and often killing children and adults alike were the familiar scourges of tuberculosis and pneumonia. Since there were no sulfonamides or antibiotics then, recovery from these diseases depended on a strong constitution and good nursing care. All too often this was not enough, as the report to the Legislature sent in by the Provincial Health Officer for 1907 proves.**

He informed them that in the past year there were 2060 cases of consumption (TB) reported with 449 deaths. The numbers for la grippe (flu) were almost as bad, 1680 cases with 66 deaths. Apparently such a high proportion of fatalities was only to be expected, for the report concludes: "The year as a whole was a somewhat ordinary one, except for the smallpox epidemic . . . ."

The smallpox epidemic – Now *that* was unusual. Once the most feared disease of all, smallpox seemed at the turn of the century to be well under control, vaccination having removed almost all its threat. While there was no law compelling vaccination in Nova Scotia, most schools refused to accept children without a certificate of immunization or a written excuse from a doctor. The result was there had been no case of smallpox in the Valley for many years. People had relaxed. Then in 1907 came the last great smallpox epidemic in the province, begun, it was said, by a sailor from a foreign ship docked in Halifax. My father told me years later of his own frightening experience.

One evening early in his first year of practice he received a phone call from Dr. Covert of Canning, who was then 'Indian Doctor'*** for the county of Kings (paid by the federal government on a fee for service basis). Dr. Covert told him that the Indians at the reservation "seemed all upset about something" and were begging him to come that very night. But it was late; he was tired; Cambridge was a long way from Canning but only about three miles from Woodville. Would Father be good enough to go to see what the fuss was all about? He would, and did, and found more trouble than either doctor had expected.

It was an unnerving experience. The young doctor, holding a smoky barn lantern for light, bent low over the head of a man whose stertorous breathing had led him to the corner of the unlit shack. To his horror he realized

*Now Mrs. Carl Atwood of Toronto, mother of the famous writer of the same name.

**The Provincial Health Officer, Dr. A. P. Reid, of Middleton, in his report to the Legislature in February, 1908, warned that the figures he gave could not be considered accurate because no law compelled physicians to send in reports and many did not bother. Statistics could only be compiled from the reports received.

***Dr. Killam later became 'Indian Doctor' himself.

that his own face was just inches away from the face of a man in the last stages of smallpox. Now he knew why the man who had led him to the house had not come in but had just set the lantern inside the door and gone hastily away. The Indians had already guessed what it was.

There was nothing he could do for that man but there was a whole band of Indians who would need help. Realizing that he must not alarm them any further lest they leave the reserve and spread the disease to other parts of the province, he told them only that the man was very sick and he would go back to his office to get the proper medicine for him. Questioning revealed that some others had similar symptons but were not nearly as ill. He promised to bring medicine for them too.

The first thing he did after he got back to his office was to vaccinate himself very thoroughly, for although he had been vaccinated four times before, the inoculations had never 'taken' and he feared he might be at risk. Then he phoned Dr. Covert. He told me that the older doctor was polite, ". . . . but I could just see the wheels turning in his head. Here is a young doctor getting all excited about a bad case of chickenpox."

But smallpox it was, one of the first cases of the worst epidemic ever documented in Nova Scotia.* Although the militia was called out to try to keep the Indians from leaving the reservation, some of them did get away and spread the infection.** According to the Provincial Health Officer, 1860 cases were reported to him, but, "Nearly all of the cases were of a very mild type and there were but five deaths. The epidemic was the worst that Nova Scotia has experienced." It was also the only time that Dr. Killam was called upon to treat smallpox.***

When he had begun to practise medicine in Woodville, my father had promised to try it for a year. By the spring of 1908 it was apparent that he was going to stay. Until now he had lived with his brother and sisters, but he was now thirty and he wanted to get married and settle down. By this time he had saved a little money so he bought the homestead consisting of the house, a barn, his father's old workshop turned woodshed, a small icehouse, and a henhouse, all standing on a little over two acres of orchard and kitchen garden. (His father, a carpenter, cabinet maker, and part owner of a small sawmill, had enjoyed experimenting with growing various kinds of vegetables and apples, pears, plums, cherries, currants, gooseberries, and even grapes and hops.) For this property he paid his brother $1,500.00, financing the deal by taking out a mortgage for $1,000.00, a loan that was not completely repaid until 1926.

The delay in paying off the mortgage was quite normal for that day and age, for money was scarce in the country and, although the doctor's fees were small, he was often not paid at all. Most of his patients were farmers or their hired men who existed miserably on subsistence wages. While the farmers themselves lived comfortably if somewhat monotonously on produce from their farms, little money changed hands. Barter was preferred, people bringing butter and eggs to exchange for sugar and tea, for example. When the merchant had collected enough of these items he would ship them to dealers in Halifax. The doctor too was often paid in produce – a cord of wood, a bushel of vegetables, a ham or bacon, or even a side of beef which was then cut up and stored in the icehouse for use in the winter. (I remember that some of the ham was extremely salty and most of the beef incredibly tough).

My father was a good doctor but a very poor bill collector. My mother, who had had business training in Toronto, kept the books but she was not allowed to send out a bill without my father's approval. Often he would say, "Cut that in half. He has had a hard year.", or "Don't send him a bill at all this year. He will try to pay it and he has a family to feed." My mother would fume a bit; she thought we needed money too.

No account of a country doctor's life would be complete without a tribute to his wife. Since his office was in his home, the doctor's wife had to double as receptionist (though she was not dignified by that name), being constantly interrupted in her other duties by the phone or door-bell. My father had chosen his helpmate wisely. Ora Webster, a local girl whom he had known since childhood, had been a school teacher (a graduate from Normal School) and a secretary in Toronto before her marriage in 1908. She served as wife, mother, housekeeper, receptionist, bookkeeper, secretary, and even as piano accompanist when her husband wanted to rehearse his part in a quartet or anthem for church choir. (Methodist, later United Church). Sometimes she had a hired girl to help her with the housework, but often she had none. Actually she preferred to "get along alone" when she could because then there was less danger of something heard or seen at the doctor's place being reported outside. The same care was taken with the children; we heard no gossip in our home.

My father, too busy and perhaps too macho to do 'woman's work', tried to lighten his wife's load in any way he could. The latest style cream separator soon replaced the old creamer, an ice-cooled refrigerator was installed, and a new washing machine was bought to lessen the drudgery of washday. Of course the separator had to be thoroughly washed and scalded every day, and the first washing machine had to be filled with pails of water heated on the stove and then operated pushing and pulling a lever by hand (often done by the hired man or girl if there was one). It was still heavy work.

Then my father had a bright idea. He had a small trapdoor cut in the floor of the kitchen and a gasoline engine

*There must have been far worse epidemics here when the white man first came to N.S. Many Indians died but no records were kept.

**I don't mean to imply that the Indians from Cambridge caused the whole epidemic!

***Although there were only a few deaths from smallpox in 1907, the epidemic caused consternation in some areas and strict quarantine was in effect. Some rather extreme measures were advocated. For instance, the Health Officer from Cape Breton, in his report suggested: a) that no one from a community having even a single case of smallpox be allowed to travel on the train; and b) that all mail coming from such an area be placed in a water-tight container and boiled for at least an hour before being sent on.!!

installed in the cellar. Just lift the trap-door, slip a belt over a pulley on the washer, go down to the basement and start the engine (vented outdoors) and – wonderful !– the hard work would be done by the machine. That contraption definitely had to be run by a man – Mother was always baffled by things mechanical.

He was never going to get rich from his practice so, like many other rural practitioners of his day, my father looked for another way of making money, one that would not involve sending bills and collecting fees from his patients. For him that led to buying in 1911 a run-down farm about a mile from his home. He paid $750.00 for it and another $600.00 for an adjoining property, planning to make his fortune – he was always an optimist – from clearing the land and growing quality apples. But first he had to make an investment of time and money. For many years that meant that instead of money from the farm supplementing what he earned as a physician, money from his practice went into the farm to upgrade it. It was an expensive hobby but he loved it. Whenever he could steal a little time from his medical duties he would drive up to the farm – no phone there – and wander through his orchard, inspecting, admiring, and planning the next improvement. It relaxed him and in addition gave him something other than illnesses to discuss with his patients.

Owning a farm meant that he had to have someone to work it, someone that is, besides his farmer brother who lived nearby and sometimes helped out. An old house on the farm served as a tenement house if the hired man was married. If he was single he was boarded, usually with us. The doctor really needed a hired man anyway to look after his two horses, his cow or cows, his two pigs, and flock of hens. In the early days of the farm there was also a big Clydesdale workhorse, Mighty Maud, who was death on other horses but gentle with children.

Life for the Killams now settled down to a somewhat predictable pattern. Each year more land was cleared and more apple trees set out. The doctor's practice grew and so did his family. Daughter Margaret had been joined by myself and little sister Joyce* and the first son, Fred, was 'on the way' when in August 1914 the First World War broke out and things changed.

Since 1912 my father had been an officer in the Medical Corps in the fall training camps for the militia of Nova Scotia. Now he joined the regular army and was promoted from lieutenant to captain. Although he answered the question, "Are you willing to serve in the Canadian Overseas Expeditionary Force?" with a "Yes", he was never sent overseas. He 'nearly killed himself', according to my mother, by trying to carry on his own practice in his time off. This was only possible because: 1) Aldershot was only about eight miles from his home; 2) he now owned a car; and 3) Camp Aldershot did not operate in the winter when the car had to be put up on blocks in the garage and horses used again. Begun in its present location in 1904, the camp had been intended merely as a summer and fall training ground for the militia and in 1914 there were still no permanent buildings. During the war temporary mess-halls and hospitals were hastily built, but the soldiers and their officers continued to be housed in thousands of bell-shaped tents, sometimes till almost Christmas. Troops from all over Canada drilled there while they waited for ships to gather in Halifax Harbour to convoy them overseas. At times there were more than seven thousand soldiers crowding the base, so even without war time casualties there was plenty of work for the Medical Corps.

The war years were strenuous times for our doctor as he struggled to do two demanding jobs. On one occasion he really did almost kill himself – from exhaustion. Returning to base one night he dozed off at the wheel and was startled awake to find his Model-T Ford being pulled sideways across a level crossing by a slowly moving freight train. The car was 'wiped off' on a telegraph pole without much damage to it or to its driver. By sheer luck he had run into the **last** car of a train just pulling away from a warehouse and not nearly up to speed. No great harm was done, but Captain Killam had no trouble staying awake for the rest of the drive!

A worse fright came for him with the Halifax explosion, in December of 1917. He was one of the doctors on the first relief train sent from Aldershot and Kentville to the stricken city. All the way there he was tormented by the near certainty that his brother Fred and his family must have been killed. After all, the Killam house on steep Kaye St. over-looked the very spot where the ill-fated ships had collided, and Fred was sure to have been home that morning, in bed ill with diphtheria.

The relief train could go no further than Rockingham because of damage to the roadbed. At the stop there, soldiers were turning away all those without urgent business in the city and providing what transportation they could to doctors, nurses, and much-needed supplies. My father was assigned a seat in a truck. "I know this is a foolish question," he said to the driver, "but do you happen to know a Fred Killam, of the Nova Scotia Nurseries?" To his surprise and relief the man did and also knew that he and his family had survived while every other family on that street had had fatalities and whole families had been wiped out. The doctor could get on with his nightmare job of giving emergency aid in the then new Camp Hill Hospital without the fear that the next victim he saw might be a member of his own family. (A sister and her family also lived in the city but not so close to the explosion site and, he thought, would have been in less danger. They also escaped, some with bad cuts.)

As the war dragged on into its fourth year there came another disaster, this time afflicting the whole world. The influenza epidemic of 1918 killed more people than four years of fierce fighting had been able to do. All the Killams, including the doctor, contracted the flu but all survived.

*Now Joyce Barkhouse of Halifax, a well-known writer, especially of stories for children of all ages.

The flu epidemic was still raging when in the fall of 1918 the world at last had some good news. The war was winding down and an armistice was about to be signed. I don't know where my father was or what he was doing on November 11, 1918, but *I* remember that day very clearly. My sister Margaret and I were helping our grandfather in Cambridge load turnips on a farm wagon when a special train from Halifax, its whistle screaming and its bell clanging continuously, rushed past the end of the field, pausing at the station just long enough to throw off a big bundle of newspapers, and then on again, its whistle still screaming. Soon the church bell began to peal. "What is it?" we asked Grandpa. "The end of the war, thank God," he said.

How wonderful it was! The War to End All Wars was finally over, and the world could settle down to a new era of peace and prosperity – we thought. □

OBITUARY

Dr. Thomas A. Anderson, (76) of Halifax, Nova Scotia died on May 27, 1992. Born in Fredericton, N.B. he received his medical degree from Dalhousie Medical School in 1943. He set up medical practice in Minto, N.B., before moving to Halifax in 1954 where he studied anaesthesia. He was an anaesthetist at the IWK Children's Hospital for 25 years, retiring in 1981. He was a member of The Medical Society of Nova Scotia. He is survived by his wife and two daughters. The *Journal* extends sincere sympathy to his wife and family.

SAINT LUKE'S DAY SERVICE

Dalhousie Medical School's
5th annual
Saint Luke's Day Service

St. Andrews United Church
(Robie & Coburg)
Halifax, N.S.

Sunday
October 18, 1992, 11:00 a.m.

Preacher: Dr. John McNab
Family Physician
Fall River, N.S.

You are all invited to attend

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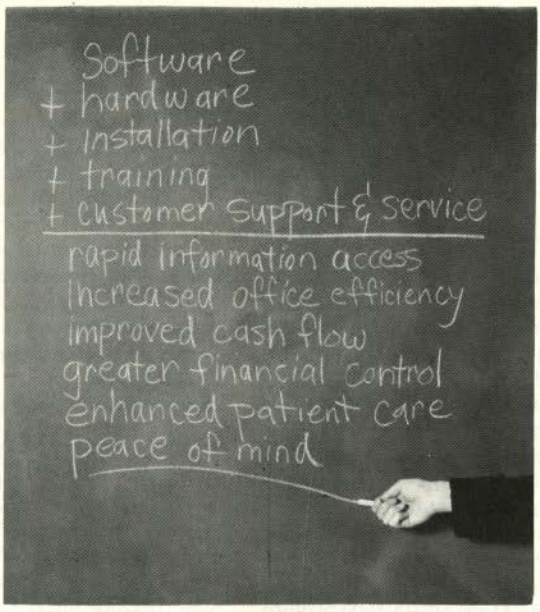

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The Medical Society of Nova Scotia has decided to formulate formal policy positions on major issues in Health Care; and this Journal will publish these as they become available. Below is the first Policy Statement. Comments are welcome.

THE MEDICAL SOCIETY OF NOVA SCOTIA
A POSITION PAPER ON HIV - HBV POLICY FOR PHYSICIANS

(Approved by MSNS Executive Committee - April 4, 1992)

There is a risk of contagion, albeit it small, between patients and physicians who are carriers of certain infectious diseases. Physicians and patients may be carriers of certain transmissible diseases such as hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

HBV carriers pose a more significant risk of contagion. This risk is increased in the health care setting where exposure prone procedures are performed.HIV carriers do not pose a measurable risk of contagion. The risk in exposure prone procedures is very low, and although not zero, cannot be measured with accuracy.

The medical profession is committed to the goal of reducing the risk of contagion to the lowest possible level. The profession recognizes that it is not possible to reduce this risk to zero.

All physicians who are engaged in exposure prone procedures:

1. Should practise universal precautions irrespective of the patient's serological status.
2. Should know their own status regarding hepatitis B virus.
3. a) If HBV negative, should obtain HBV immunization.

   b) If HBV positive, should consult an expert panel, as per the Center for Disease Control guidelines of June of 1991, regarding appropriate limits to practice.

All physicians who have engaged in high risk behaviors are advised to determine their status regarding HIV. HIV positive physicians, who perform exposure prone procedures, should consult an expert panel to determine limits to practice.

Physicians who are carriers of HIV or HBV or any other transmissible disease, are entitled to the same ethical considerations as any patient. i.e.. Testing should only be carried out with informed consent and in absolute confidence.

Physicians who are carriers of HIV and who do not engage in exposure prone procedures, pose no significant, measurable risk to the public. The Medical Society supports their ability to continue their practice within these guidelines and will make this support known to the public.

Physicians are advised to obtain disability insurance with express provision protecting them if they cannot practise their specific medical work.

Physicians, who are HIV or HBV positive, may lose their ability to practise as a result of expert panel advice or because of social reaction. In either case, they are disabled and should receive benefits appropriate to their loss.

The Medical Society recognizes the social stigmata which may affect the physician who carries an infectious disease.

The Medical Society is committed to the holistic support of those physicians. This would specifically include the provision of a support group or groups initiated and organized by the Society. The Society is committed to developing a fund to provide monetary support for these physicians. This monetary support would not be intended to duplicate disability benefits but rather would provide for expenses related to possible retraining and relocation.

BuSpar*
(buspirone HCl)

A New Class of Anxiolytic for Todays Active Patients.

THERAPEUTIC CLASSIFICATION
Antianxiety Agent

INDICATIONS AND CLINICAL USE
Short term symptomatic relief of excessive anxiety in patients with generalized anxiety disorder (psychoneurotic disorder).

Eight three-way, short term, controlled clinical trials involving buspirone, diazepam and placebo are considered central to the evaluation of buspirone as an anxiolytic agent. In four of the eight clinical trials, buspirone demonstrated a significant difference from placebo. In the other four trials, there was no significant difference between buspirone and placebo, but a significantly greater improvement was observed with diazepam than with placebo. The adverse effect profiles of buspirone and diazepam in these clinical trials were, however, different.

CONTRAINDICATIONS
BuSpar (buspirone hydrochloride) is contraindicated in patients hypersensitive to buspirone hydrochloride.

BuSpar is contraindicated in patients with severe hepatic or severe renal impairment.

WARNINGS
The occurrence of elevated blood pressure in patients receiving both BuSpar (buspirone hydrochloride) and a monoamine oxidase inhibitor (MAOI) has been reported. Therefore, it is recommended that buspirone should not be used concomitantly with a MAOI.

Since buspirone can bind to central dopaminergic receptors, the possibility of acute and chronic changes in dopamine mediated neurological function (e.g. dystonia, pseudo-parkinsonism, akathisia and tardive dyskinesia) should be considered. (SEE PRECAUTIONS)

Since the effects of buspirone have not been evaluated in patients with a history of convulsive disorders and since it lacks anticonvulsant activity in animals, buspirone is not recommended for patients with seizure disorders.

Use of Buspirone in Patients Previously Treated with a Benzodiazepine: Patients who have previously taken benzodiazepines may be less likely to respond to buspirone than those who have not. In two clinical studies to date, substitution of buspirone did not ameliorate or prevent withdrawal symptoms in either abrupt or gradual withdrawal from various benzodiazepines following long-term use. Therefore, if it is considered desirable to switch a patient who has been receiving benzodiazepine therapy to buspirone, the benzodiazepine should first be withdrawn gradually. A drug-free interval is desirable between withdrawal of the benzodiazepine and initiation of buspirone, in order to increase the likelihood of distinguishing between benzodiazepine withdrawal effects and unrelieved anxiety due to possible failure of buspirone in this category of patients.

Benzodiazepine rebound or withdrawal symptoms may occur over varying time periods depending in part on the type of drug and its effective half-life of elimination. These symptoms may appear as any combination of irritability, anxiety, agitation, insomnia, tremor, abdominal cramps, muscle cramps, vomiting, sweating, flu-like symptoms without fever and, occasionally, seizures, and should be treated symptomatically.

Use in Pregnancy and Lactation: The safety of buspirone during pregnancy and lactation has not been established and, therefore, it should not be used in women of childbearing potential or nursing mothers, unless, in the opinion of the physician, the potential benefits to the patient outweigh the possible hazards to the fetus. Buspirone and its metabolites are excreted in milk in rats. The extent of excretion in human milk has not yet been determined.

PRECAUTIONS
Effects on Cognitive and Motor Performance: In controlled studies in healthy volunteers, single doses of buspirone up to 20 mg had little effect on most tests of cognitive and psychomotor function, although performance on a vigilance task was impaired in a dose-related manner. The effect of higher single doses of buspirone on psychomotor performance has not been investigated.

Ten (10) mg of buspirone given three times daily for seven days to healthy volunteers produced considerable subjective sedation but no significant effect on psychomotor performance (no vigilance tasks were used in this study). It also caused transient dizziness, especially on standing and walking.

Until further experience is obtained with buspirone, patients should be warned not to operate an automobile or undertake activities requiring mental alertness, judgement and physical coordination, until they are reasonably certain that buspirone does not affect them adversely.

Significant Interactions: In laboratory studies in healthy volunteers, buspirone in doses up to 20 mg did not potentiate the psychomotor impairment produced by relatively modest doses of alcohol. However, decreased contentedness or dysphoria was observed with a combination of alcohol and a 20 mg single dose of buspirone. Since no data are available on concomitant use of higher doses of buspirone and alcohol, it is prudent to advise patients to avoid alcohol during buspirone therapy.

Food increased the bioavailability of unchanged buspirone in healthy subjects, possibly due to a reduced first-pass effect.

Concomitant use of monoamine oxidase inhibitors and buspirone has been reported to cause an increase in blood pressure. Therefore, concomitant use of these medications is not recommended.

In a study in normal volunteers, no interaction of buspirone with amitriptyline was seen. A similar study with diazepam showed an increase in the levels of nordiazepam.

In another study in normal volunteers, concomitant administration of buspirone and haloperidol resulted in increased serum haloperidol concentrations. The clinical significance of this finding is not clear.

There is one report suggesting that the concomitant use of trazodone and buspirone may have caused 3- to 6-fold elevations in SGPT (ALT) in a few patients. In a similar study, attempting to replicate this finding, no interactive effect on hepatic transaminases was identified.

Because the effects of concomitant administration of buspirone with most other psychotropic drugs have not been studied, the concomitant use of buspirone with other CNS active drugs should be approached with caution.

In vitro, buspirone does not displace tightly bound drugs like phenytoin, propranolol and warfarin from serum proteins. However, there has been one report of prolonged prothrombin time when buspirone was added to the regimen of a patient treated with warfarin. The patient was also chronically receiving phenytoin, phenobarbital, digoxin and Synthroid. In vitro, buspirone may displace less firmly bound drugs like digoxin. The clinical significance of this property is unknown.

There have been no reports to date of interference of buspirone with commonly employed clinical laboratory tests.

Drug Abuse and Dependence: Although preliminary animal and human investigations suggest that buspirone may be significantly devoid of potential for producing physical or psychological dependence, only extensive clinical experience with the drug will provide conclusive evidence. Meanwhile, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of buspirone misuse and abuse.

Use in Patients with Impaired Hepatic or Renal Function: Since it is metabolized by the liver and excreted by the kidneys, buspirone should be used with caution in patients with a history of hepatic or renal impairment. It is contraindicated in patients with severe hepatic or renal impairment.

Use in Children: The safety and effectiveness of buspirone in individuals below the age of 18 years have not been established.

Use in the Elderly: Buspirone has not been systematically evaluated in older patients. Although it would appear from limited pharmacokinetic and clinical studies that buspirone does not behave differently in the elderly, there is little known about the effects of buspirone in this age group at doses above 30 mg/day. Therefore, it is recommended that buspirone should be used in the elderly at doses not exceeding 30 mg/day for a duration not exceeding 4 weeks.

Neuroendocrine Effects: Single doses of 30 mg or higher of buspirone resulted in significantly elevated plasma prolactin and growth hormone concentrations in normal volunteers. No effect was seen at lower doses. In another study, no such increases were observed after buspirone was administered in divided doses (10 mg t.i.d.) for 28 days.

Possible Concerns Related to Buspirone's Binding To Dopamine Receptors: Because buspirone can bind to central dopamine receptors, a question has been raised about its potential to cause acute and chronic changes in dopamine mediated neurological function (e.g., dystonia, pseudo-parkinsonism, akathisia, and tardive dyskinesia). Clinical experience in controlled trials has failed to identify any significant neuroleptic-like activity; however, a syndrome of restlessness, appearing shortly after initiation of treatment, has been reported in some small fraction of buspirone treated patients. The syndrome may be explained in several ways. For example, buspirone may increase central noradrenergic activity; alternatively, the effect may be attributable to dopaminergic effects (i.e., represent akathisia). Obviously, the question cannot be totally resolved at this point in time. Generally, long-term sequelae of any drug's use can be identified only after several years of marketing.

ADVERSE REACTIONS
The most common adverse reactions encountered with BuSpar (buspirone hydrochloride) are dizziness, headache, drowsiness and nausea. During premarketing clinical trials, approximately 10% of the patients discontinued treatment due to an adverse event.

Adverse reactions reported include the following:

CNS: Dizziness, headache, drowsiness, lightheadedness, insomnia, fatigue, nervousness, decreased concentration, excitement, depression, confusion, nightmares/vivid dreams, anger/hostility. Infrequently (<1%) depersonalization, noise intolerance, euphoria/feeling high, dissociative reaction, fear, loss of interest, dysphoria, hallucinations, seizures, suicidal thoughts. Rarely, slurred speech, claustrophobia, cold intolerance, stupor, psychosis.

Neurologic: Paresthesia, weakness, incoordination, tremor, numbness. Infrequently, muscle cramps and spasms, rigid/stiff muscles, involuntary movements, akathisia, slowed reaction time. Rarely, tingling of limbs, stiff neck, rigidity of jaw, ataxia.

Autonomic: Dry mouth, sweating/clamminess, blurred vision, constipation. Infrequently, urinary frequency, retention and burning, flushing.

Cardiovascular: Tachycardia, chest pain, palpitations. Infrequently, syncope, hypotension, hypertension. Rarely, congestive heart failure, cerebrovascular accident, myocardial infarction, cardiomyopathy, bradycardia, EKG change.

Gastrointestinal: Nausea, G.I. distress, diarrhea, vomiting. Infrequently, flatulence, increased appetite, anorexia, hypersalivation, rectal bleeding, irritable colon. Rarely, burning tongue.

Respiratory: Nasal congestion. Infrequently, shortness of breath, chest congestion, difficulty breathing, hyperventilation. Rarely, epistaxis.

Endocrine: Infrequently, decreased and increased libido, weight gain, weight loss, menstrual irregularity/breakthrough bleeding. Rarely, delayed ejaculation, impotence, galactorrhea, amenorrhea, thyroid abnormality.

Allergic or Toxic: Skin rash, sore throat. Infrequently, edema/facial edema, pruritus, chills/fever. Rarely, photophobia, erythema, flu-like symptoms.

Clinical Laboratory: Infrequently, increases in liver enzymes. Rarely, eosinophilia, leukopenia, thrombocytopenia.

Miscellaneous: Tinnitus, muscle aches/pains. Infrequently, redness/itching of eyes, altered taste/smell, roaring sensation in head, malaise, easy bruising, dry skin, arthralgia, blisters, hair loss. Rarely, acne, thinning of nails, sore eyes, inner ear abnormality, pressure on eyes, nocturia, enuresis, hiccups, voice loss, alcohol abuse.

Post Introduction Clinical Experience: Post-marketing experience in the United States has shown an adverse experience profile similar to that given above. Additional reports have included rare occurrences of allergic reaction, cogwheel rigidity, dystonic reaction, ecchymosis, emotional lability and tunnel vision. Because of the uncontrolled nature of these spontaneous reports, a causal relationship to buspirone treatment has not been determined.

SYMPTOMS AND TREATMENT OF OVERDOSAGE
Symptoms: In clinical pharmacology trials, BuSpar (buspirone hydrochloride) up to 400 mg/day was administered to healthy male volunteers. As this dose was approached, the following symptoms were observed in descending order of frequency: drowsiness, ataxia, nausea and vomiting, dizziness, clammy feeling, difficulty thinking, feeling "high", "rushing" sensation, gastric distress, headache, itching, miosis, hypotension, tremor, incoordination, insomnia and hallucinations. In a dose ranging study in acute psychotic patients, up to 2400 mg/day was administered. Dizziness, nausea and vomiting were the most common adverse effects. One patient developed extrapyramidal symptoms at 600 mg/day.

Treatment: There is no specific antidote for buspirone. Management should, therefore, be symptomatic and supportive. Any patient suspected of having taken an overdose should be admitted to a hospital as soon as possible, and the stomach emptied by gastric lavage. Respiration, pulse and blood pressure should be monitored, as in all cases of drug overdosage. As with the management of intentional overdosage with any drug, the ingestion of multiple agents should be suspected. In six anuric patients, hemodialysis either had no effect on the pharmacokinetics of buspirone or decreased its clearance.

DOSAGE AND ADMINISTRATION
BuSpar (buspirone hydrochloride) dosage should be individually adjusted, according to tolerance and response.

The recommended initial dose is 5 mg two to three times daily. This may be titrated according to the needs of the patient and the daily dose increased by 5 mg increments every two or three days up to a maximum of 45 mg daily in divided doses. The usual therapeutic dose is 20 to 30 mg daily in two or three divided doses.

Elderly Patients: Limited pharmacokinetic and clinical data have shown no difference in the effects of buspirone between elderly patients and healthy adult volunteers. However, until more information has accumulated in the elderly, it is recommended that the maximum daily dose should not exceed 30 mg for a duration not exceeding 4 weeks.

Note: If buspirone is administered to patients with compromised hepatic or renal function, careful monitoring will be required together with appropriate dosage adjustment.

AVAILABILITY
BuSpar (buspirone hydrochloride) Tablets, 10 mg, are white tablets. Bottles of 100.

Product Monograph available upon request.

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†Until further experience is obtained with buspirone, patients should be warned not to operate an automobile or undertake activities requiring mental alertness, judgement or physical co-ordination until they are reasonably certain that buspirone does not affect them adversely.

††Since no data is available on concomitant use of higher doses of buspirone and alcohol, it is prudent to advise patients to avoid alcohol during buspirone therapy.

*T.M. Authorized user, Bristol-Myers Squibb Canada Inc.

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PMAC

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TILADE®

Nedocromil Sodium Inhalation Aerosol
2mg/metered dose

THERAPEUTIC CLASSIFICATION
Bronchial Anti-inflammatory Agent

ACTIONS AND CLINICAL PHARMACOLOGY
TILADE (nedocromil sodium) is a new chemical entity that inhibits the release of inflammatory mediators from a variety of cell types occurring in the lumen and in the mucosa of the bronchial tree. When it is administered topically to the bronchi, it displays specific anti-inflammatory properties. Laboratory experiments have shown that nedocromil sodium prevents the release of inflammatory chemotactic and smooth muscle contracting mediators, which are preformed or derived from arachidonic acid metabolism by both the lipoxygenase and cyclo-oxygenase pathways, in a range of human and animal leucocytes. Nedocromil sodium prevents the release of mediators, such as, histamine, Leukotriene C_4 (LTC_4) and Prostaglandin D_2 (PGD_2) from the cellular population of the chronically inflamed bronchus, especially from mast cells of the mucosal type. There is growing evidence that these mediators are important in human lung disease, and TILADE may, therefore, be expected to have more scope in the management of chronic reversible obstructive airways disease in which allergy, inflammation and bronchial hyperresponsiveness are significant pathophysiological factors.

After inhalation, TILADE is deposited throughout the respiratory tract where about 5% of the dose is absorbed. Because TILADE is inhaled much of the delivered dose is either swallowed directly or subsequently due to mucociliary clearance from the large airways. A small amount of nedocromil sodium (2 to 3%) is then absorbed from the gastrointestinal tract. Since the absorption rate constant from the respiratory tract is lower than the elimination rate constant in bile and urine, the terminal half-life (1.5 to 2 hours) reflects the absorption rate of the lungs. The drug is cleared rapidly enough from the circulation such that successive doses in the recommended dosing regimen do not accumulate.

Nedocromil sodium is bound reversibly (80%) to human plasma proteins and to a lesser extent in animals. It is not metabolized in man or in animals. In man it is excreted unchanged in the urine (approximately 70%) and in faeces (approximately 30%). While the plasma concentration falls rapidly (i.e., to 10% of peak levels in 8 hours) and urinary excretion is 90% complete within 12 hours, faecal elimination may take up to 3 days to be completed.

The pharmacokinetic profile of nedocromil sodium is similar in healthy volunteers and in patients with reversible obstructive airways disease. In challenge studies, a single dose of TILADE provided protection against bronchospasm provoked by stimulants such as, inhaled allergens, cold air, exercise and atmospheric pollutants.

INDICATIONS AND CLINICAL USE
TILADE (nedocromil sodium) is indicated as an adjunctive in the treatment of mild to moderate reversible obstructive airways disease, including bronchial asthma and bronchitis, particularly where allergic factors may be present.

TILADE can also be used on a maintenance or on an occasional basis in the prevention of bronchospasm provoked by stimulants, such as, inhaled allergens, cold air, exercise and atmospheric pollutants.

TILADE may be used safely with other anti-asthma drugs. The addition of TILADE may permit reduction of concomitant therapy.

CONTRAINDICATIONS
Known hypersensitivity to TILADE (nedocromil sodium), to sorbitan trioleate or to propellants such as dichlorotetraflourethane and dichlorodiflouromethane.

WARNINGS
TILADE (nedocromil sodium) should not be used for the relief of an acute attack of bronchospasm.

PRECAUTIONS
IN THE TREATMENT OF ASTHMA, TILADE (nedocromil sodium) SHOULD NOT BE USED AS AN ALTERNATIVE TO BRONCHODILATORS. However, addition of TILADE to the treatment regimen can reduce the need for concomitant medications. **This reduction should be done slowly and under close supervision. The requirements for the reduction of corticosteroids have not been established.**

To ensure optimal delivery to the bronchial tree patients should be carefully instructed in the proper use of the inhaler. For maximum benefit, patients should be reminded of the necessity to take TILADE regularly, as prescribed.

Abuse of fluorocarbon propellants may be hazardous. Deliberate inhalation of propellants in high concentrations, particularly under conditions of hypoxia, has resulted in toxic cardiovascular effects, severe CNS disturbances, and death. Acute toxic effects of TILADE would be restricted to propellant overdose or to aerosol induced bronchoconstriction. Nedocromil sodium itself has an extremely low acute toxicity.

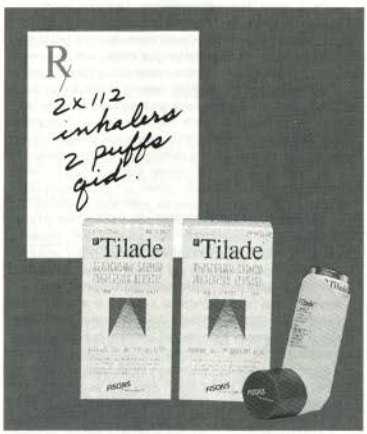
Use in Pregnancy Safety in human pregnancy and the absence of adverse effects on the human reproductive process have not been established. Small amounts are known to cross the placenta but without effect in animals. In fact, in reproductive studies, nedocromil sodium at up to 100mg/kg (more than 800 times the human maintenance dose) has shown no teratogenic or embryotoxic effects, nor has it interfered with reproductive performance, gestation, parturition, or suckling. Nedocromil sodium did not affect male or female fertility nor did it alter the development of progeny.

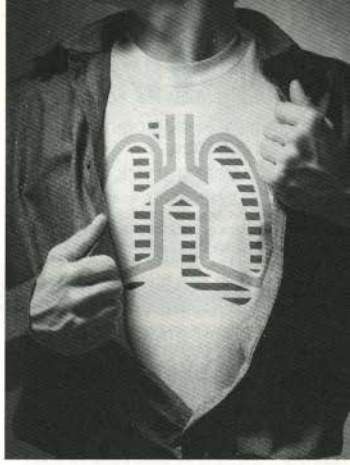
Although there is no reason to suspect that nedocromil sodium affects the fetus or mother, as with any drug, caution must be exercised. The benefits of treatment to the mother must be weighed against the potential risk to the fetus before proposing its use.

Nursing Mothers Safety in breast-fed infants has not been established. Animal studies have indicated no toxicity of nedocromil sodium in suckling newborns receiving drug from the parent or directly by injection. The concentrations of nedocromil sodium in milk of animals were very low but have not been measured in human milk.

The benefits of treating a nursing mother must be weighed against potential risk to the infant.

Use in Children The safety and efficacy of TILADE in children under twelve years of age has not yet been established.





Drug Interactions TILADE has been used in association with oth antiasthmatic drugs in man including β_2-adrenergic agonists, inhal and oral corticosteroids, theophylline and other methylxanthin and, with ipratropium bromide. No drug-drug interactions have be observed in humans or in animals.

ADVERSE REACTIONS
Few side effects have been reported, principally unpleasant tas headache and nausea, that have been mild and transient a insufficient to require discontinuation of treatment in nearly cases.

Specific side effects and their frequencies of occurrence wi chronic dosing are unpleasant taste 13.4%, headache 4.8%, naus 3.8% and vomiting 1.1%.

SYMPTOMS AND TREATMENT OF OVERDOSE
There have been no reported cases of overdosage in huma Animal studies have not shown evidence of toxic effects of TILA (nedocromil sodium), even at high dosage. If overdosage is suspect treatment should be supportive and directed to the control of t relevant symptoms.

DOSAGE AND ADMINISTRATION
TILADE (nedocromil sodium) is intended for regular daily usage a should not be used for relief of symptoms during an acute attack

The therapeutic benefits of repeated doses of TILADE will apparent in most patients within one week of starting treatment, b it may take longer on occasion.

Adults and children over 12 years of age: In initial a maintenance therapy, two actuations (4mg of nedocromil sodiu four times daily. Some patients can be maintained with two actuatio twice daily.

TILADE in a single dose of two actuations (4mg) a few minut before exposure provides protection against bronchospasm provok by stimulants, such as, inhaled allergens, cold air, exercise a atmospheric pollutants.

DOSAGE FORM
Each 17mL pressurized, aluminium canister contains nedocrom sodium and sorbitan trioleate as surfactant with dichlorotetraflu thane and dichlorodifluoromethane as propellants. Units are fill with material to provide a minimum of 112 metered actuatio delivering 2mg of nedocromil sodium. The pack consists of aerosol canister with a plastic adaptor and a patient instructi sheet.

Product monograph available upon request.

REFERENCES: 1. Bianco S et al, *Respiration* 1989; 56:204-1
2. Tilade product monograph 1990.

FISONS
Pharmaceuticals

Fisons Corporation Limited
1851 Sandstone Manor
Pickering, Ontario
L1W 3R9

Tilade®

Pr One a day Oruvail®

Sustained-release ketoprofen capsules 150 mg and 200 mg

Anti-inflammatory analgesic agent

ACTION and CLINICAL PHARMACOLOGY: Animal pharmacological studies have shown that ketoprofen possesses anti-inflammatory, analgesic and antipyretic properties. The anti-inflammatory action is not mediated through the pituitary adrenal axis. Its therapeutic effectiveness has been demonstrated by a reduction in joint swelling, pain and duration of morning stiffness, and by increased grip strength and an improvement in functional capacity. Clinical trials in patients with rheumatoid arthritis and osteoarthritis have shown that when given in a dose of 200 mg once daily, the anti-arthritic activity of Oruvail is comparable to that of a twice daily administration of ketoprofen (100 mg ketoprofen b.i.d.). Ketoprofen 200 mg daily induced less gastrointestinal bleeding than acetylsalicylic acid 4 g/day. **Pharmacokinetics properties:** Ketoprofen from Oruvail is slowly but almost completely absorbed from the gastrointestinal tract. Mean peak plasma levels of 2.2 and 4.2 mg/L are achieved about 5 hours following single oral doses of Oruvail 100 and 200 mg, respectively. Pharmacokinetics are linear over a dosage range of 100 to 200 mg. The systemic availability of Oruvail is 95% of that of conventional capsules. In a food-effect study, meal composition did not affect the extent of absorption of ketoprofen from Oruvail, although a heavy meal slightly but significantly delayed the absorption of the drug by about 2 hours by comparison to a light meal; in this study, there was no comparison with the fasted state nor with a conventional ketoprofen formulation. Steady-state plasma ketoprofen concentrations are achieved within 4 days with mean peak and trough levels of 4.3 and 0.91 mg/L respectively, after repeated doses of 200 mg once daily. There is some evidence that C_{max} and bioavailability are increased in the elderly as the result of an age-related reduction in volume of distribution since the apparent elimination half-life of about 8 hours is similar in both young and elderly patients. No or negligible accumulation of ketoprofen was found following repeated once daily dosing of Oruvail 200 mg capsules in either young or aged subjects. In arthritic patients treated with Oruvail 200 mg once daily for up to 3 months, the steady-state disposition of ketoprofen remains unaltered during chronic administration. When comparing to a group of healthy subjects, no differences with respect to AUC, C_{max}, and elimination half-life were found, indicating that inflammatory joint disease has no influence on the kinetics of Oruvail capsules.

INDICATIONS and CLINICAL USES: Oruvail (ketoprofen) is indicated in the treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis.

CONTRAINDICATIONS: Oruvail (ketoprofen) is contraindicated in patients with active peptic ulcers or active inflammatory diseases of the gastrointestinal tract. Oruvail is also contraindicated in patients who have demonstrated hypersensitivity to the drug. Because of cross-sensitivity, ketoprofen should not be given to patients in whom acetylsalicylic acid (ASA) and other nonsteroidal anti-inflammatory drugs induce symptoms of asthma, rhinitis or urticaria. Fatal anaphylactoid reactions have occurred in such individuals.

WARNINGS: Peptic ulceration, perforation and gastrointestinal bleeding, sometimes severe and occasionally fatal have been reported during therapy with nonsteroidal anti-inflammatory drugs (NSAID's), including Oruvail (ketoprofen). Unlike most adverse reactions, which usually manifest themselves in the first month if they are going to occur in an individual, new peptic ulcers keep appearing in patients under treatment with ketoprofen at a rate of greater than 1% per year. Oruvail should be given under close medical supervision to patients prone to gastrointestinal tract irritation particularly those with a history of peptic ulcer, diverticulosis or other inflammatory disease of the gastrointestinal tract. In these cases the physician must weigh the benefits of treatment against the possible hazards. Patients taking any NSAID including this drug should be instructed to contact a physician immediately if they experience symptoms or signs suggestive of peptic ulceration or gastrointestinal bleeding. These reactions can occur without warning symptoms or signs and at any time during the treatment. Elderly, frail and debilitated patients appear to be at higher risk from a variety of adverse reactions from nonsteroidal anti-inflammatory drugs (NSAID's). For such patients, consideration should be given to a starting dose lower than usual, with individual adjustment when necessary and under close supervision. See "Precautions" for further advice. **Use in Pregnancy:** The safety of Oruvail when administered to pregnant or nursing women has not been determined and therefore such use is not recommended. Pregnant rats who received ketoprofen 6 and 9 mg/kg/day p.o. from day 15 of gestation, showed dystocia and increased pup mortality. **Nursing mothers:** In rats, ketoprofen at doses of 9 mg/kg (approximately 1.5 times the maximum human therapeutic dose) did not affect perinatal development. Upon administration to lactating dogs, the milk concentration of ketoprofen was found to be 4 to 5% of the plasma drug level. Data on secretion in human milk after ingestion of ketoprofen do not exist. As with other drugs that are excreted in milk, Oruvail is not recommended for use in nursing mothers. **Use in Children:** The conditions for safe and effective use of Oruvail in children under 12 years of age have not been established and the drug is therefore not recommended in this age group.

PRECAUTIONS: Gastrointestinal system: If peptic ulceration is suspected or confirmed, or if gastrointestinal bleeding or perforation occurs Oruvail (ketoprofen) should be discontinued, an appropriate treatment instituted and patient closely monitored. There is no definitive evidence that the concomitant administration of histamine H_2-receptor antagonists and/or antacids will either prevent the occurrence of gastrointestinal side effects or allow continuation of Oruvail therapy when and if these adverse reactions appear. **Renal function:** As with other nonsteroidal anti-inflammatory drugs, long-term administration of ketoprofen to animals has resulted in renal papillary necrosis and other abnormal renal pathology. In humans, there have been reports of acute interstitial nephritis with hematuria, proteinuria, and occasionally nephrotic syndrome. A second form of renal toxicity has been seen in patients with prerenal conditions leading to the reduction in renal blood flow or blood volume, where the renal prostaglandins have a supportive role in the maintenance of renal perfusion. In these patients, administration of a nonsteroidal anti-inflammatory drug may cause a dose-dependent reduction in prostaglandin formation and may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics, and the elderly. Discontinuation of nonsteroidal anti-inflammatory therapy is usually followed by recovery to the pre-treatment state. Ketoprofen and its metabolites are eliminated primarily by the kidneys, therefore the drug should be used with great caution in patients with impaired renal function. In these cases lower doses of Oruvail should be anticipated and patients carefully monitored. During long-term therapy kidney function should be monitored periodically. **Hepatic function:** As with other nonsteroidal anti-inflammatory drugs, borderline elevations of one or more liver tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy. Meaningful (3 times the upper limit of normal) elevations of ALT or AST occurred in controlled clinical trials in less than 1% of patients. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of more severe hepatic reaction while on therapy with this drug. Severe hepatic reactions including jaundice and cases of fatal hepatitis have been reported with this drug as with other nonsteroidal anti-inflammatory drugs. Although such reactions are rare, if abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), this drug should be discontinued. During long-term therapy, liver function tests should be monitored periodically. If this drug is to be used in the presence of impaired liver function, it must be done under strict observation. **Fluid and Electrolyte Balance:** Fluid retention and edema have been observed in approximately 2% of patients treated with ketoprofen. Therefore, as with many other nonsteroidal anti-inflammatory drugs, the possibility of precipitating congestive heart failure in elderly patients or those with compromised cardiac function should be born in mind. Oruvail should be used with caution in patients with heart failure, hypertension or other conditions predisposing to fluid retention. Serum electrolytes should be monitored periodically during long-term therapy, especially in those patients at risk. **Hematology:** Drugs inhibiting prostaglandin biosynthesis do interfere with platelet function to some degree; therefore, patients who may be adversely affected by such an action should be carefully observed when Oruvail is administered. Blood dyscrasias associated with the use of nonsteroidal anti-inflammatory drugs are rare, but could be with severe consequences. Anemia is commonly observed in rheumatoid arthritis and is sometimes aggravated by nonsteroidal anti-inflammatory drugs, which may produce fluid retention or minor gastrointestinal blood loss in some patients. Therefore, patients with initial hemoglobin values of 10 g/dL or less who are to receive long-term therapy should have hemoglobin values determined frequently. **Infection:** In common with other anti-inflammatory drugs, Oruvail may mask the usual signs of infection. **Ophthalmology:** Blurred and/or diminished vision has been reported with the use of ketoprofen and other nonsteroidal anti-inflammatory drugs. If such symptoms develop this drug should be discontinued and an ophthalmologic examination performed; ophthalmic examination should be carried out at periodic intervals in any patient receiving this drug for an extended period of time. **Drug Interactions: Methotrexate:** The concomitant administration of ketoprofen and high-dose methotrexate has been associated with prolonged and marked enhancement of serum methotrexate levels resulting in severe methotrexate toxicity. This may also apply to some other nonsteroidal anti-inflammatory drugs. There were no abnormalities in methotrexate kinetics or evidence of toxicity when ketoprofen was given at least 12 hours after completion of high-dose methotrexate infusion. ORUVAIL should not be used in patients receiving high dose methotrexate. The potential for severe toxicity should be kept in mind when prescribing ketoprofen and low-dose methotrexate concurrently. ORUVAIL should not be administered within 12 hours of methotrexate infusion. **Acetylsalicylic acid (ASA):** concurrent administration of ASA decreased ketoprofen protein binding and increased its plasma clearance. The overall result was a 40% reduction in the AUC of ketoprofen. **Oral anticoagulants:** Ketoprofen has been shown to depress platelet aggregation and it can prolong bleeding time by approximately 3 to 4 minutes from baseline values. However, a study conducted in twenty patients undergoing therapy with coumarin and simultaneously receiving ketoprofen, failed to demonstrate potentiation of anticoagulant effect. Nevertheless, close monitoring of patients is recommended when Oruvail is given concomitantly with anticoagulants. **Diuretics:** hydrochlorothiazide, given concomitantly with ketoprofen, produces a reduction in urinary potassium and chloride excretion compared to hydrochlorothiazide alone. Patients taking diuretics are at greater risk of developing renal failure secondary to a decrease in renal blood flow caused by prostaglandin inhibition. **Antacids:** concomitant administration of magnesium hydroxide and aluminum hydroxide does not interfere with the rate or extent of the absorption of ketoprofen. **Lithium:** nonsteroidal anti-inflammatory agents have been reported to increase steady-state plasma lithium levels. It is recommended that plasma lithium levels be monitored when Oruvail is coadministered with lithium. **Probenecid:** concurrent administration of probenecid increases both free and bound ketoprofen through reducing the plasma clearance of ketoprofen to about one-third as well as decreasing its protein binding. ORUVAIL is not recommended in association with probenecid. Ketoprofen is extensively (99%) protein bound to human serum albumin and may compete for binding sites with drugs such as sulfonamides, oral hypoglycemic agents, phenytoin or lithium. Although no significant interaction has been documented, patients with such combination therapy should be monitored. **Clinical Laboratory Test:** The presence of ketoprofen and its metabolites in urine has been shown to interfere with certain tests which are used to detect albumin, bile salts, 17-ketosteroids or 17-hydroxycorticosteroids in urine and which rely upon acid precipitation as an end point or upon colour reactions for carbonyl groups. No interference was seen in the tests for proteinuria using Albustix, Hema-Combistix or Labstix Reagent Strips. Ketoprofen decreases platelet adhesion and aggregation. Therefore, it can prolong bleeding time by approximately 3 to 4 minutes from baseline values. There is no significant change in platelet count, prothrombin time, partial thromboplastin time, or thrombin time.

ADVERSE REACTIONS: Gastrointestinal: Gastrointestinal effects were the most frequently observed adverse reactions and were seen in approximately 13% of patients receiving Oruvail (ketoprofen). Ulceration and gastrointestinal bleeding have been observed in a few patients receiving Oruvail therapy (approximately 0.3%). Other adverse reactions in order of decreasing frequency were: gastrointestinal pain, dyspepsia, constipation, nausea and/or vomiting, diarrhea and flatulence. Such symptoms led to the discontinuation of treatment in 6.8% of patients. **Central Nervous System:** Central nervous system adverse reactions were next in frequency and included headache, fatigue, drowsiness, dizziness, depression, restlessness and nightmares. **Skin:** rash, eczema, flushing, pruritus, sweating and loss of hair were occasionally observed. **Allergic:** These were seen infrequently and included urticaria, angioedema and asthma. **Cardiovascular:** Mild peripheral edema, palpitation, bruising, arrhythmia, chest pain and exacerbation of circulatory disturbances were reported. **Auditory:** Tinnitus and deafness were reported on rare occasions. **Mouth:** The following symptoms were reported: dry mouth, mouth ulcers, sore tongue and inflammation of the mouth and gums. **Laboratory tests:** Abnormal alkaline phosphatase lactic dehydrogenase, glutamic oxaloacetic transaminase and blood urea nitrogen values were found in some patients receiving ketoprofen therapy. The abnormalities did not lead to discontinuation of treatment and, in some cases, returned to normal despite continuation of the drug. There have been sporadic reports of decreased hematocrit and hemoglobin values without progressive deterioration on prolonged administration of the drug.

SYMPTOMS AND TREATMENT OF OVERDOSE: Symptoms: Of 20 cases of overdosage (up to 5,000 mg) reported in Great Britain (5 children, 14 adolescents or young adults, and 1 elderly), only 4 had mild symptoms (vomiting in 3, drowsiness in 1 child). **Treatment:** Administer gastric lavage or an emetic and treat symptomatically: compensate for dehydration, monitor urinary excretion and correct acidosis if present. The drug is dialyzable; therefore, hemodialysis may be useful to remove circulating drug and to assist in case of renal failure.

DOSAGE AND ADMINISTRATION: Adults: The usual dosage is 150 to 200 mg once daily. The capsules should be taken with food and can be administered in the morning or evening. **Elderly and debilitated patients:** The dosage should be reduced in patients with impaired renal function and the elderly. The lower strength should be used in those cases. **Children:** Oruvail is not indicated in children under 12 years of age because clinical experience in this age group is insufficient.

Composition: Non medicinal ingredients: colloidal silicone dioxide, ethyl cellulose, gelatin, maize starch, shellac, sucrose, talc. Colouring agents: ORUVAIL 150 mg: erythrosine, titanium dioxide. ORUVAIL 200 mg: brilliant blue, erythrosine, titanium dioxide.

AVAILABILITY: Oruvail 150 capsules: each transparent pink capsule with opaque white cap (each half printed "Oruvail 150" in black) contains ketoprofen 150 mg as white pellets. Available in bottles of 100 and 250. **Oruvail 200 capsules:** each transparent pink capsule with opaque blue cap (each half printed "Oruvail 200" in yellow) contains ketoprofen 200 mg as white pellets. Available in bottles of 100 and 250.

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7. Data on File: May & Baker, 1991. 2-57022-15-03/91(E).

Pr One a day Oruvail® 150

Sustained-release ketoprofen capsules 150 mg

MAY & BAKER PHARMA
RHÔNE-POULENC RORER

RHÔNE-POULENC RORER CANADA INC.
MONTREAL, QUEBEC

PAAB

MEMBER PMAC

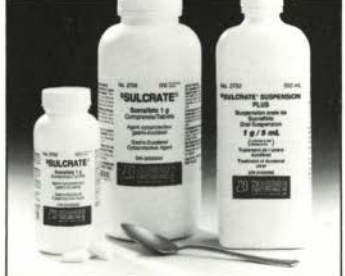
Product monograph available to physicians and pharmacists upon request.

NON-SYSTEMIC

Pr SULCRATE®

sucralfate/NORDIC

PRESCRIBING INFORMATION



THERAPEUTIC CLASSIFICATION

Gastroduodenal Cytoprotective Agent

ACTIONS AND CLINICAL PHARMACOLOGY

SULCRATE® (sucralfate) exerts a generalized gastric cytoprotective effect by enhancing natural mucosal defence mechanisms. Studies conducted in animals and clinical trials in humans have demonstrated that sucralfate can protect the gastric mucosa against various irritants such as alcohol, ASA, hydrochloric acid, sodium hydroxide or sodium taurocholate.

In addition, sucralfate has been demonstrated to have a greater affinity for ulcerated gastric or duodenal mucosa than for non-ulcerated mucosa.

Sucralfate produces an adherent and cytoprotective barrier at the ulcer site. This barrier protects the ulcer site from the potential ulcerogenic properties of acid, pepsin and bile. Furthermore, sucralfate blocks acid diffusion across the sucralfate protein barrier and also complexes directly with pepsin and bile.

The action of sucralfate is non-systemic as the drug is only minimally absorbed from the gastrointestinal tract. The minute amounts of the sulfated disaccharide which are absorbed are primarily excreted in the urine.

Each gram of sucralfate contains approximately 200 mg of aluminum. The aluminum moiety can dissociate at low pH and aluminum release in the stomach can be expected; however, aluminum is poorly absorbed from the intact gastrointestinal tract. Following administration of 1 g of sucralfate (tablets or suspension) four times a day to individuals with normal renal function, approximately 0.001% to 0.017% of sucralfate's aluminum content is absorbed and excreted in the urine. This results in an aluminum load of between 0.008 mg and 0.136 mg following a 4 g daily dose. Individuals with normal renal function excrete absorbed aluminum and can respond to an increased aluminum load by increasing urinary excretion. These values were determined in individuals with intact gastrointestinal mucosa. Available evidence does not indicate that absorption of aluminum would be different in individuals with ulcerated gastrointestinal mucosa.

Experiments have shown that sucralfate is not an antacid.

INDICATIONS AND CLINICAL USE

1. **Tablets** SULCRATE® (sucralfate) tablets are indicated for the treatment of duodenal and non-malignant gastric ulcer.

SULCRATE® tablets are also indicated for the prophylaxis of duodenal ulcer recurrence.

2. **Suspension** SULCRATE® suspension and SULCRATE® SUSPENSION PLUS are indicated for the treatment of duodenal ulcer.

CONTRAINDICATIONS

There are no known contraindications to the use of SULCRATE® (sucralfate). However, the physician should read the "WARNINGS" section when considering the use of this drug in pregnant or pediatric patients, or patients of childbearing potential.

WARNINGS

Use in Pregnancy There has been no experience to date with the use of SULCRATE® (sucralfate) in pregnant women. Therefore, sucralfate should not be used in pregnant women or women of childbearing potential unless, in the judgment of the physician, the anticipated benefits outweigh the potential risk.

Pediatric Use Clinical experience in children is limited. Therefore, sucralfate therapy cannot be recommended for children under 18 unless, in the judgment of the physician, anticipated benefits outweigh the potential risk.

PRECAUTIONS

General The following should be taken into account before treating patients with SULCRATE® (sucralfate):

Recurrence may be observed in patients after a successful course of treatment for gastric or duodenal ulcers. While the treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the underlying cause of ulcer disease.

Proper diagnosis is important since symptomatic response to sucralfate therapy does not rule out the presence of a gastric malignancy.

Drug Interactions Antacids should not be taken within half an hour before or after sucralfate intake because of the possibility of decreased binding of sucralfate with the gastro-duodenal mucosa as a consequence of a change of intra-gastric pH.

Animal studies have shown that simultaneous administration of sucralfate with tetracycline, phenytoin or cimetidine results in a statistically significant reduction in the bioavailability of these agents. Cimetidine absorption was not reduced in humans. In clinical trials, the concomitant administration of sucralfate reduced the bioavailability of digoxin.

These interactions appear to be non-systemic and to result from the binding of sucralfate to the concomitantly administered drug in the gastrointestinal tract. In all cases, complete bioavailability was restored by separating the administration of sucralfate from that of the other agent by 2 hours.

Sucralfate, administered respectively 30 and 60 minutes before ASA or ibuprofen did not alter the bioavailability of those agents. In a study comparing the prior administration of a single dose of sucralfate tablets on the bioavailability of naproxen, indomethacin or ketoprofen versus administration in the absence of sucralfate, it was shown that the total amount of these drugs absorbed was not altered; however, the peak concentration of each was reduced, and the time to reach peak concentration was delayed. A single dose of SULCRATE® SUSPENSION PLUS administered one-half hour before naproxen had a similar effect on the bioavailability of naproxen.

The physician should consider the possible clinical implications of these interactions. It is recommended to separate the administration of any drug from that of sucralfate when the potential for altered bioavailability is felt to be critical to the effectiveness of that drug.

Unless specified, the above data are based on studies carried out with SULCRATE® tablets.

Chronic Renal Failure

Dialyzed Patients – Sucralfate should be used with caution in patients with chronic renal failure. When sucralfate is administered orally, small amounts of aluminum are absorbed from the gastrointestinal tract (see ACTIONS AND CLINICAL PHARMACOLOGY). Existing evidence indicates that patients with normal renal function receiving the recommended doses of sucralfate adequately excrete aluminum in the urine; however, patients with chronic renal failure or those receiving dialysis have impaired excretion of absorbed aluminum, and in these individuals, aluminum is known to accumulate in serum and in tissues. In particular, dialysis patients are at greater risk as aluminum does not cross dialysis membranes of the dialysis machine since it is bound to plasma proteins, most notably albumin and transferrin.

In patients with chronic renal failure undergoing dialysis, aluminum-related toxicity (encephalopathy and aluminum-related bone disease), associated with the administration of sucralfate and/or other sources of aluminum has been reported. Consideration should therefore be given to the total daily load of aluminum before administering sucralfate in combination with other aluminum-containing medications, such as aluminum-containing antacids.

Nondialyzed Patients – In a study of six nondialyzed chronic renal failure patients with glomerular filtration rates ranging from approximately 10 to 40% of normal, sucralfate administered at a dose of 1 g QID for three weeks resulted in elevated serum aluminum concentrations which plateaued at approximately 23 μg/L after one week of treatment from a pretreatment level of 3 μg/L. Renal aluminum clearance increased in relation to the increase in serum levels and returned to baseline within two weeks following discontinuation of sucralfate as did serum aluminum concentrations. No adverse events were reported in these patients.

These data indicate that the use of sucralfate in nondialysed chronic renal failure patients requires physician discretion since the excretion of absorbed aluminum may be impaired in these individuals.

ADVERSE REACTIONS

1. **SULCRATE® Tablets and Suspension** Very few side effects have been reported with SULCRATE® (sucralfate) tablets and suspension. They are mild in nature and have only exceptionally led to discontinuation of therapy.

The main complaint has been constipation ranging from 1.7% to 3.3% of patients.

Other side effects reported included diarrhea, nausea, gastric discomfort, indigestion, dry mouth, skin rash, pruritus, back pain, dizziness, sleepiness and vertigo.

2. **SULCRATE® SUSPENSION PLUS** In a placebo-controlled clinical trial involving 184 patients, the adverse event rates for SULCRATE® SUSPENSION PLUS was similar to that seen in the placebo group (SULCRATE® SUSPENSION PLUS 10.2% vs placebo 7.4%). The most common adverse event was headache (3.4%) followed by nausea (2.3%), abdominal pain (2.3%), constipation (1.1%), diarrhea (1.1%), and urticaria (1.1%). Only headache, abdominal pain and nausea had a higher incidence in the SULCRATE® SUSPENSION PLUS group relative to placebo.

See the PRECAUTIONS section for information on the potential for aluminum toxicity in dialyzed chronic renal failure patients.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Overdosage has never been observed with SULCRATE® (sucralfate) and appears to be unlikely since, using maximal doses of up to 12 g/kg/body weight in a variety of animal species, a lethal dose could not be established.

Overdosage is likely to be associated with symptoms similar to those described in the ADVERSE REACTION section, such as constipation. These should be treated symptomatically.

DOSAGE AND ADMINISTRATION

1. **Tablets** The recommended adult oral dosage of SULCRATE® (sucralfate) for duodenal and gastric ulcer is one tablet of 1 g four times a day, one hour before meals and at bedtime, on an empty stomach. For duodenal ulcer, SULCRATE® may also be administered as two 1 g tablets twice daily, on waking and at bedtime on an empty stomach.

In duodenal ulcers, while healing with SULCRATE® often occurs within two to four weeks, treatment should be continued for a maximum of 8 to 12 weeks unless healing has been demonstrated by X-Ray and/or endoscopic examination.

In the case of gastric ulcers, an alternative treatment should be considered if no objective improvement is observed following 6 weeks of SULCRATE® therapy. However, patients with a large gastric ulcer that has demonstrated a progressive healing tendency may require an additional 6 weeks of treatment.

For the prophylaxis of duodenal ulcer recurrence, the recommended dosage is one tablet of 1 g twice daily, on an empty stomach. Treatment may be continued for up to one year.

For relief of pain, antacids may be added to the treatment. However, antacids should not be taken within ½-hour before or after SULCRATE® intake.

2. **Suspensions** *a. SULCRATE® Suspension (500 mg/5 mL)* The recommended adult oral dosage of SULCRATE® (sucralfate) suspension for the treatment of (acute) duodenal ulcer is 1 g (10 mL) four times a day on an empty stomach before meals and at bedtime, or 2 g (20 mL) twice a day on waking and at bedtime on an empty stomach.

b. SULCRATE® SUSPENSION PLUS (1 g/5 mL) The recommended adult dose of SULCRATE® SUSPENSION PLUS for the treatment of (acute) duodenal ulcer is 2 g (10 mL) twice a day on waking and at bedtime on an empty stomach.

Duration of continuous treatment in patients with chronic renal failure receiving dialysis should be evaluated by periodic monitoring of serum aluminum levels, due to the possibility of aluminum accumulation in these patients (see PRECAUTIONS). According to information widely available in the literature, patients with serum aluminum concentrations that approach 100 μg/L should be carefully monitored for symptoms of aluminum toxicity and treatment should be discontinued if such symptoms appear.

There is no evidence to indicate that patients with chronic renal failure, who do not require dialysis, are at risk of developing aluminum toxicity while receiving the recommended doses of sucralfate. Physician discretion should be exercised when considering the duration of treatment (see PRECAUTIONS).

AVAILABILITY

1. **Tablets** Each white, capsule-shaped, compressed tablet, monogrammed "SULCRATE®" on one side and "NORDIC" on the other side, contains 1 g of sucralfate. To be kept and dispensed in a well-closed container. Bottles of 100 and 500 tablets.

2. **Suspensions** *a. SULCRATE® Suspension* Each 5 mL of pink suspension contains 500 mg of sucralfate. Supplied in bottles of 400 mL. Shake well before using. Store at room temperature. Avoid freezing.

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