

## Radiation oncology in Canada: the increasing manpower crisis

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Cancer has been the second most common cause of death in Canada for decades, and its nonsurgical management has largely been carried out by radiation oncologists for many years. Most of these specialists are not Canadian medical graduates, and the supply of suitably trained radiation oncologists is steadily diminishing in relation to the increasing numbers of patients referred to regional cancer centres. Consequently, the workload of each radiation oncologist has steadily increased to a level well beyond that recommended internationally, and it is still increasing. Unless more Canadian graduates can be attracted into the field, and unless more staff positions can be created in virtually all Canadian regional cancer centres, the high quality of patient care, teaching and research offered by radiation oncologists will suffer irreparably and will probably never recover to its former internationally recognized level. In this paper the author recommends ways in which to increase the number of radiation oncologists, though to be

effective they will require the collaboration of provincial governments, medical schools, provincial cancer foundations and the medical profession.

Depuis plusieurs décennies, le cancer est au deuxième rang des causes de décès au Canada. Son traitement non-opératoire relève depuis longtemps surtout des oncologues-radiothérapeutes. La plupart d'entre eux ne sont pas diplômés en médecine au Canada; le nombre des spécialistes bien formés dans cette discipline diminue constamment en regard du nombre croissant des malades adressés aux centres régionaux de traitement du cancer, d'où augmentation constante, et encore sensible actuellement, de la somme de travail de chaque radiothérapeute, qui dépasse nettement les normes reconnues de par le monde. Si nous ne parvenons pas à intéresser un plus grand nombre de nos diplômés à cette spécialité et à créer plus de postes dans presque tous ces centres, nous assisterons à une détérioration probablement irréparable de la haute qualité des soins, de l'enseignement et de la recherche qu'on a universellement reconnue à nos oncologues-radiothérapeutes. L'auteur propose des moyens d'augmenter le nombre de ceux-ci. Le succès dépendra de la collaboration qui existera entre les gouvernements provinciaux, les facultés de médecine, les fondations provinciales du cancer et la profession médicale.

Our national mortality statistics have for many years shown that the second most common cause of death in Canada is malignant disease.

With a few exceptions, the incidence of cancer at various sites has not fallen significantly, and in several very important sites (notably the lung) the incidence is rising. The specialist care of patients with malignant disease has been carried out largely by surgeons and by radiation oncologists in all parts of Canada for many years; more recently the newly emerging specialists in medical oncology have given invaluable assistance, initially with hematologic malignant diseases and later with solid tumours. There is no major shortfall in the number of surgeons or medical oncologists in Canada, but there has been for many years an increasingly severe shortage of radiation oncologists.<sup>1</sup> This shortage is fully recognized by the agencies and foundations responsible for provincial cancer care and by several provincial governments,<sup>2</sup> but it is not generally known to physicians and medical students in this country or elsewhere.<sup>3</sup>

In addition to curative therapy, a large part of the noncurative management of patients with cancer falls to the radiation oncologist. This involves not only the continuing follow-up of treated patients<sup>4</sup> but also a direct responsibility for palliative and terminal care, often for the balance of the patient's life. The shortage of radiation oncologists in this country has now reached crisis proportions, and the situation has been rendered doubly critical by the fact that so few Canadian medical graduates enter the field of radiation oncology.<sup>5</sup>

With the gradually increasing cooperation now apparent between surgeons, medical oncologists and

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radiation oncologists, the multidisciplinary management of cancer has led to many advances in the control of the disease, as a result of which more patients with cancer are now cured, and many more survive in greater comfort for longer than they would have in past years. Radiation therapy remains the best method of curative treatment for many patients, and it offers better palliation than any other modality for most patients with incurable disease.<sup>6,7</sup>

Radiation oncology has, for a variety of reasons, been the specialty into which the recruitment of suitably trained graduates has been most difficult in this country.<sup>8</sup> As a result, ongoing research into optimizing the quality and timing of radiation therapy, maintenance of adequate clinical staffing to provide patient care, undergraduate education and postgraduate training have suffered. The shortage of radiation oncologists has in recent years been such that some educational programs in some university centres have had to be discontinued, foreign-trained medical graduates have had to be hired on an emergency basis in several centres, and radiotherapeutic services in one centre have virtually collapsed. In addition, the shortage has been compounded by a persistent and apparently increasing trend for newly qualified Canadian specialists to emigrate from Canada.<sup>4</sup>

At the request of the Advisory

Council in Radiation Oncology of the Canadian Association of Radiologists (ACRO), a national survey of all Canadian radiotherapy centres was made in 1982-83.<sup>5</sup> Requested were the number of new patients referred, the number of radiation oncologists on staff and the proportion of Canadian to foreign medical graduates on staff in each centre from 1963 to 1982. Additional material was obtained from the annual reports published by the various cancer foundations and agencies, notably those in Ontario from 1939 on, and from other sources listed in the references of this paper. Information on population was obtained from Statistics Canada whenever possible, and the medical school from which each Canadian radiation oncologist graduated was confirmed from the 1983 edition of the "Canadian Medical Directory" (Southam, Don Mills, Ont.).

#### Patient workload

Patient care is the primary responsibility of virtually all radiation oncologists in Canada, and in nearly all situations each individual cancer centre has no control over the number of patients referred for advice, treatment and follow-up examinations, since all such patients are referred by their own physicians. As the proportion of the population in

older groups increases, as the population increases and as the number of malignant diseases in which radiation therapy may play a valuable role increases, the number of patients referred to each regional cancer centre increases. For example, we know from the annual reports of the Ontario Cancer Treatment and Research Foundation that the number of new patients treated by radiation rose from a few hundred in 1939 to almost 11 000 in 1980. From the 1982-83 ACRO survey we know that nationally the number of patients treated by radiation oncologists increased from 30 466 in 1976 to 33 491 in 1980, or just under 2% per year.<sup>5</sup> With the increase in population since 1980 we have no reason to believe that this rate of increase will lessen during the next decade, since the proportion of Canadians entering the main cancer-bearing age groups is increasing faster than the population is at present. It is also becoming apparent that radiation therapy can help more patients than was formerly thought.<sup>6,7</sup>

Over the past quarter century many national and international recommendations have been made on the optimum number of new cancer patients a radiation oncologist should see in consultation and treat each year. The initial five recommendations, published in tabular form,<sup>1</sup> provide average figures of 7.5

**Table I—Recent recommendations for radiation oncology staffing in North American cancer centres**

<p>National Committee on Physician Manpower<sup>1</sup> Ontario Council of Health<sup>2</sup> (with other information from refs. 1 and 3)</p>	<p>One radiation oncologist:121 000 population Optimal work-year for a radiation oncologist of 1840 hours, which was calculated as equivalent to 206 patients.</p>	<p>Recommendation made in 1975 for 1981. Recommendation made in 1983 to the provincial government from a 1974 study at Princess Margaret Hospital, Toronto. No allowance made for teaching, research or administration.</p>
<p>Diagnosis and Treatment Committee, Ontario Cancer Treatment and Research Foundation<sup>9</sup> National Cancer Institute, US National Institutes of Health<sup>10</sup></p>	<p>Average of 179 patients over four teaching centres and three nonteaching centres. One radiation oncologist in chief per centre, plus one radiation oncologist for each 200 to 250 new patients treated per year.</p>	<p>Internal report made in 1980. A maximum of 15% of working time was allotted to teaching. One of the definitive US documents published in 1981. The report states that additional staff will be needed for primary patient care, education and research.</p>
<p>US Department of Health and Human Services<sup>11</sup></p>	<p>Annual work-year of 2116 hours, which was calculated as equivalent to around 233 patients for a nonteaching oncologist and 120 to 130 for an academic oncologist, who should spend only 50% of his or her time in patient care.</p>	<p>A follow-up to a report on US physician manpower for 1990, by which time, it was projected, 400 academic faculty and 2126 nonacademic physicians would be needed. The current shortfall is calculated at just under 20% of this, or about 450 radiation oncologists.</p>

radiation oncologists per million people, or approximately 220 new patients per radiation oncologist per year. Since the last of these recommendations was made in 1972, several others have appeared (Table I).<sup>1,2,9-11</sup> From these, I believe it is reasonable to aim at a new patient

workload per radiation oncologist per year of 160 in an academic teaching centre and 220 in a non-teaching centre. I believe that the optimal workload should be expressed this way rather than as a ratio of radiation oncologists to population because of changing inci-

dence and referral patterns in patients with malignant disease.

I have discussed optimal workloads up until now. What then have been and are the realities of the Canadian situation? Data from the ACRO survey<sup>5</sup> for teaching and nonteaching centres respectively are

**Table II—Number of new patients treated by each radiation oncologist in Canadian training centres,\* 1963–82<sup>5</sup>**

Year	British Columbia			Ontario				Quebec			National average
	Alberta	Manitoba	Centre 1	Centre 2	Centre 3	Centre 4	Centre 1	Centre 2	Centre 3		
1963	213	394	174	378	369	222	135	NA	NA	NA	245
1964	215	305	177	412	305	243	149	NA	NA	NA	258
1965	235	267	183	431	324	259	141	NA	NA	NA	263
1966	200	242	178	338	255	243	141	NA	NA	NA	228
1967	225	219	185	348	264	229	142	NA	386	NA	250
1968	236	247	167	338	258	250	151	NA	386	NA	254
1969	246	410	172	310	275	253	158	NA	400	NA	278
1970	447	150	197	314	274	237	162	NA	429	NA	276
1971	417	148	198	371	320	229	160	NA	375	NA	277
1972	456	196	197	277	290	345	192	NA	400	NA	294
1973	472	208	216	272	283	253	153	NA	400	NA	282
1974	388	213	213	317	273	278	212	NA	412	333	293
1975	390	164	203	339	325	302	201	NA	367	534	314
1976	379	193	200	340	312	274	168	395	378	460	310
1977	302	235	240	324	281	275	177	432	350	493	311
1978	314	191	232	346	282	200	186	467	360	404	298
1979	325	157	231	362	320	209	193	475	370	373	301
1980	313	167	190	314	307	213	195	518	345	391	295
1981	349	177	227	255	271	NA	180	457	364	317	289
1982	365	162	212	348	NA	NA	NA	550	342	424	343

\*Training centres are those with postgraduate radiation oncology training programs. NA = not available.

**Table III—Number of new patients treated by each radiation oncologist in Canadian nonteaching centres,\* 1963–82<sup>5</sup>**

Year	British Columbia		Saskatchewan		Ontario			Quebec	New Brunswick	Nova Scotia	Prince Edward Island	Newfoundland	National average
	Alberta	Centre 1	Centre 2	Centre 1	Centre 2	Centre 3							
1963	352	NA	403	570	221	265	240	NA	233	NA	180	NA	308
1964	377	NA	266	291	286	269	246	NA	233	NA	163	NA	266
1965	363	NA	281	440	305	412	252	NA	257	NA	175	NA	311
1966	419	NA	388	434	325	381	249	NA	251	NA	142	NA	324
1967	364	NA	292	474	376	409	289	NA	236	NA	172	NA	326
1968	366	NA	308	419	363	375	255	NA	259	NA	210	NA	319
1969	350	NA	291	340	346	394	207	NA	258	NA	189	NA	297
1970	379	238	378	359	367	395	211	172	291	NA	198	NA	299
1971	458	244	523	351	275	405	204	247	340	NA	215	230	317
1972	465	256	464	372	335	405	236	269	302	NA	178	227	319
1973	463	258	236	386	375	423	247	312	343	NA	150	223	311
1974	483	293	237	370	283	466	248	358	275	NA	156	213	307
1975	521	302	281	210	195	443	250	449	279	NA	109	257	300
1976	547	254	399	159	231	409	216	510	265	329	60	242	302
1977	377	229	658	184	201	392	272	620	237	335	143	220	322
1978	387	246	728	340	185	391	294	461	262	447	121	248	342
1979	398	239	723	383	179	395	296	240	288	258	95	250	312
1980	432	283	555	424	151	375	357	275	295	239	81	286	313
1981	272	261	384	200	NA	404	NA	326	251	193	101	276	267
1982	267	271	647	NA	NA	NA	NA	656	324	269	136	245	352

\*Nonteaching centres are those without postgraduate radiation oncology training programs.

presented in Tables II and III, from which it can be seen that in only three of the teaching centres and two of the nonteaching centres was the workload for radiation oncologists even close to optimal consistently over the 20 years surveyed. The national average for teaching centres was approximately twice what it should have been during that time, and for nonteaching centres it was approximately 50% greater than it should have been. It is also apparent that the situation worsened more in the teaching centres than in the nonteaching centres over the last 7 years of the survey period, and this undoubtedly had an effect on post-graduate education, undergraduate education and research, the prime functions that necessitate a lower workload in these centres. These disturbing facts are due solely to a chronic shortage of radiation oncologists in this country, a shortage that is also apparent elsewhere in North America.<sup>12</sup>

#### Sources of radiation oncologists

The recruitment of Canadian medical graduates into the field of radiation oncology over the last quarter century has been extremely poor<sup>5</sup> (Table IV). The proportion of these graduates among radiation oncologists in Canadian centres exceeds 50% only in Quebec, and in

most of the western provinces the proportion has been close to zero for decades. Most of the foreign medical graduates recruited as radiation oncologists in Canada are Commonwealth graduates trained either in their home countries or in the United Kingdom, and many of the older recruited Canadian medical graduates also received much of their training in the United Kingdom.<sup>4</sup> It is not surprising that in a recent survey of all candidates sitting the examinations of the Royal College of Physicians and Surgeons of Canada<sup>13</sup> the group sitting the radiation oncology exams had the highest percentage of foreign medical graduates. However, many radiation oncologists in Canada still are not certificants or fellows of the Canadian Royal College but are provincially licensed to practise, having passed either the appropriate American board examination or the Royal College examination of their own country. The provincial licensing boards have regularly recognized their own shortages of radiation oncologists and have also recognized that without radiation oncologists from foreign medical schools radiation therapy services in their provinces would have completely collapsed long ago.

In 1975 it was stated that until such time as Canadian training programs were producing an adequate

number of radiation oncologists continued reliance would have to be placed on the immigration of fully trained radiation oncologists; immigration of such physicians would have to be encouraged, but this would be difficult, as there was no surplus in the Commonwealth, Europe or the United States.<sup>1</sup> This remains true today in view of the failure of all but a few radiation oncology training programs to attract Canadian medical graduates into the specialty and in view of the ever increasing difficulties encountered in trying to attract fully trained foreign medical graduates to a radiation oncology practice in Canada.<sup>4</sup> In general, the economic realities and practice conditions have greatly improved in the countries that were the traditional sources of radiation oncologists for Canada, and these very improvements are now attracting out of this country at an alarming rate Canadian-trained oncologists who are graduates of Canadian medical schools. Of the 215 physicians who obtained their CRPC or FRCPC in radiation oncology between 1955 and 1982 at least 90 have been "lost", since only 116 were in full-time practice in Canada at the end of 1982, and some of the 116 had obtained their Canadian qualifications before 1955 or never obtained them.<sup>5,14</sup>

**Table IV—Percentage of radiation oncologists in Canadian centres between 1963 and 1982 who graduated from Canadian medical schools**

Year	British Columbia	Alberta	Saskatchewan	Manitoba	Ontario	Quebec	Maritimes and Newfoundland
1963	43	50	100	14	54	NA	25
1964	43	50	67	14	43	NA	25
1965	43	0	67	14	43	NA	25
1966	37	0	80	14	42	NA	25
1967	37	0	67	14	52	100	25
1968	37	0	67	12	50	100	25
1969	37	0	67	12	47	100	25
1970	37	0	60	0	45	100	40
1971	33	0	75	0	44	92	43
1972	33	0	75	0	43	92	37
1973	33	0	29	0	43	92	37
1974	36	0	29	0	45	93	33
1975	33	0	14	0	41	93	33
1976	33	0	0	0	40	80	31
1977	27	0	0	0	39	81	31
1978	29	9	0	0	37	77	33
1979	36	8	0	0	43	83	31
1980	33	9	0	0	45	75	38
1981	25	17	14	0	42	81	33
1982	25	24	0	0	43	80	40

## Reasons for the shortage of radiation oncologists

Many explanations have been put forward nationally and internationally for the chronic and worsening shortage of radiation oncologists, but very few studies or surveys have been reported. One factor generally agreed to be of major importance is the widespread ignorance of the specialty among both medical students<sup>3,15,16</sup> and physicians, which is largely due to inadequate exposure to oncology in general and radiation oncology in particular at the undergraduate level.<sup>3,4,16,17</sup> This inadequacy is general throughout Canada and the United States and is made worse by the lack of radiation oncologists for teaching and for acting as role models in virtually all teaching centres in Canada, even where medical students have access to cancer clinics and to the practice of radiation oncology. As a result of this inadequate exposure, very few graduating physicians have any idea what functions a radiation oncologist fulfils, other than the often biased and inaccurate views expressed by their teachers in "more important and major" specialties to which these students were exposed in medical school.<sup>3</sup> What you never see or understand you will rarely have any interest in or motivation towards.<sup>15</sup> And yet there is a wealth of enjoyable, fascinating and worthwhile medical practice available in the field of oncology<sup>15</sup> — in both aca-

demical and nonteaching centres — as well as a vast amount of clinical and basic research to be done.<sup>7,16,18</sup>

Few Canadian medical schools have a department of oncology. There are a few departments of radiation oncology, but in many centres radiation oncologists find themselves part of a subdivision of diagnostic radiology, an allotment that is certainly reasonable on purely historical grounds but is entirely inappropriate on clinical grounds. Data gathered in 1983 for the Canadian Oncology Society revealed that 7 of the 16 Canadian medical schools studied had either a subdivision of oncology in the internal medicine department or the surgery department or a separate department of oncology (H.R. Shibata, R.N. MacDonald: unpublished data). Within these 16 schools there are opportunities for students to take electives in the regional cancer centre; in only 2 schools do more than 25% of the students actually take these electives, and in some schools less than 10% of the students do so. In eight of the schools there is a course in clinical oncology, but an average of only 2 hours is devoted to radiation oncology throughout the entire undergraduate curriculum.

It is therefore no surprise to learn from a recent Ontario survey of undergraduates taking summer electives in provincial cancer clinics that well over 50% of the responding students felt that outside of this elective experience their undergrad-

uate oncologic education was deficient in both quantity and quality.<sup>19</sup> In my view, bearing in mind that malignant disease is so frequent a cause of disability, suffering and death, every medical school in this country should have a department of oncology with appropriate undergraduate and postgraduate programs.<sup>12</sup>

University curriculum committees are besieged by requests for more teaching time from expanding specialties; however, since they are usually hampered by the time-honoured allotments of teaching time to fields such as medicine, surgery, pediatrics, psychiatry, obstetrics and gynecology, and family practice they find it difficult to accede to newer needs. In most schools multidisciplinary oncology teaching does not exist to any significant degree, and where it does exist it is usually regarded as a minor specialty. It is to be hoped that this will change.

Until the widespread ignorance of modern clinical oncology is dissipated, there will continue to be what in many cases amounts to a psychological block against the consideration of a career in oncology. Certainly, not every graduate is psychologically prepared for the emotional stress of such a career, but at present most graduates have very little idea of what such a career might be like, and their undergraduate education does little to relieve this ignorance.<sup>16</sup> Of course, the choice of radiation oncology means that it will be neces-

Table V—Population statistics\* and required numbers of radiation oncologists†

Province	1976		1981		1990		2000	
	Population	ROR	Population	ROR	Population	ROR	Population	ROR
British Columbia	2 466 605	20	2 744 470	23	3 033 900	25	3 376 100	28
Alberta	1 838 040	15	2 237 725	18	2 515 400	21	2 864 100	24
Saskatchewan	921 325	8	968 310	8	1 020 500	8	1 056 800	9
Manitoba	1 021 505	8	1 026 245	8	1 107 900	9	1 147 600	9
Ontario	8 264 455	68	8 625 110	71	9 806 300	81	10 681 000	88
Quebec	6 234 445	52	6 438 400	53	6 739 800	56	6 883 200	57
New Brunswick	677 250	6	696 405	6	768 400	6	810 000	7
Nova Scotia	828 570	7	847 445	7	908 400	7	944 900	8
Prince Edward Island	118 230	1	122 510	1	135 100	1	143 200	1
Newfoundland	557 725	5	567 680	5	610 400	5	629 500	5
Canada‡	22 992 500	190	24 343 180	201	26 741 400	221	28 646 400	237

\*Population figures and future estimates supplied by Statistics Canada.

†ROR = radiation oncologists required, calculated on the basis of 1 per 121 000 population.

‡Each population figure in this row includes the populations of the Yukon and the Northwest Territories, which do not have radiotherapy centres, and therefore exceeds the sum of the provincial figures above it.

sary to become familiar with both radiobiology and medical physics, although not at a level beyond the ability of the average medical graduate. Having this knowledge does not isolate the radiation oncologist from his or her peers in other specialties, particularly in those centres where multidisciplinary management is the standard practice, even though the apparatus necessary to treat patients must be physically isolated from other hospital departments.

### **Estimate of Canada's needs for radiation oncologists**

The calculated needs of each of Canada's provinces for radiation oncologists between 1976 and 2000 are shown graphically in Table V. The 1981 total for radiation oncologists in full-time practice, according to the 1983 ACRO survey,<sup>5</sup> was actually 128, a shortfall of 73 from the optimal figure. The national total in 1984 was no greater. Nationally, therefore, we are at least 50% short of our needs, and the shortage appears to be maximal in Quebec (Tables II and III).

Recently submitted data indicate that there are insufficient numbers of residents in training in Royal College approved programs to meet our shortage even if all residents passed their certification examinations.<sup>4,14</sup> Approximately 60% do pass, which reflects the relatively high proportion (33%) of foreign medical graduates currently in these programs.<sup>13</sup> Allowing for the expected retirements of the many senior radiation oncologists in all provinces,<sup>4,17</sup> Canada needs another 150 radiation oncologists by 1990 and probably a further 45 by 2000, and to even come close to these needs all of the provincial training programs must be expanded considerably.<sup>4</sup> An increase in undergraduate and new graduate exposure is required so that more Canadian medical graduates will be interested in the specialty as a career, and there must be further overseas recruitment of fully trained radiation oncologists in the short term to meet the ever increasing demands.

Up until now I have not discussed the research needs of radiation oncology specifically; however, it is

increasingly a sorry fact that the radiotherapy service workloads of virtually all Canadian cancer centres have all but eliminated any worthwhile attempts at radiation research in the last several years. It may come as a shock to readers to learn that, despite being intrinsically and potentially one of the wealthiest Western nations, Canada now ranks 13th internationally in per-capita spending on cancer research. Governments and their advisers bear strong responsibility for this regrettable fact, but it is equally true that our medical schools must accept some responsibility because of their lack of support of excellent interdisciplinary oncology education programs for undergraduates and graduates.

Oncology is not a minor specialty — cancer is the second largest killer in our nation. Medical schools cannot truly claim to be thoroughly and broadly educating their trainees for the present and future needs of the country when they pay very little attention to malignant disease and to its prevention and optimal management.<sup>18</sup> For Canada to resume its proper place in the cancer research pantheon federal and provincial governments, medical schools, regional cancer foundations and organizations, and the medical profession must realize that malignant disease is not going to disappear. There are not enough clinicians and researchers working on all aspects of the disease, and as far as radiation oncology is concerned the crisis is here and now.

### **Recommendations**

- There must be immediate recognition by the medical profession that there is a very serious shortage of fully trained radiation oncologists in this country, which is steadily worsening because of the increase in the number of patients and the decrease in the number of graduates entering the field. The short-term necessity of attracting foreign medical graduates is becoming increasingly difficult economically, as is the retention of trained Canadian medical graduates. This must be addressed by the appropriate universities and cancer foundations across the country.

- Immediate efforts should be made by medical schools, cancer foundations and the various government agencies responsible for health care to ensure that there are enough well trained radiation oncologists in their oncology departments to provide optimal patient care, to fulfil clinical and basic research interests and to expose the specialty to undergraduates. All this must be done within a framework of competitive working conditions that is comparable to that of other clinical specialties.

- Every Canadian medical school should establish a department or division of oncology, with multidisciplinary representation. Such departments should have full teaching responsibilities for undergraduates and should set up postgraduate training programs in the oncologic subspecialties — notably radiation oncology, surgical oncology and medical oncology — whenever possible.

- Postgraduate training programs in radiation oncology must be expanded to provide Canada with adequate numbers of specialists for the future, since the patient population is expected to continue increasing beyond the turn of the century. Only 45 residents were in training across Canada in December 1983. The number should probably be doubled for at least 6 years to come close to supplying this country's needs by 1990, although it could then be reduced somewhat.

I am grateful to all of my colleagues across Canada for supplying data and for their opinions and advice. Special thanks to Drs. Henry R. Shibata and R. Neil MacDonald for their information on undergraduate oncology education in Canada, to Dr. J. Lester McCallum and his staff in the Office of Training and Evaluation at the Royal College of Physicians and Surgeons of Canada for their compilation of examination data, and to Dr. J. Stewart Lott and all of my ACRO colleagues for their advice and guidance.

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### Indications

**APRESOLINE Oral:** Essential hypertension. APRESOLINE is used in conjunction with a diuretic and/or other antihypertensive drugs but may be used as the initial agent in those patients in whom, in the judgment of the physician, treatment should be started with a vasodilator.  
**APRESOLINE Parenteral:** Severe hypertension when the drug cannot be given orally or when there is an urgent need to lower blood pressure (e.g. toxemia of pregnancy or acute glomerulonephritis). It should be used with caution in patients with cerebral vascular accidents.

### Contraindications

Hypersensitivity to hydralazine, coronary artery disease, mitral valvular rheumatic heart disease, and acute dissecting aneurysm of the aorta.

### Warnings

Hydralazine may produce in a few patients a clinical picture simulating systemic lupus erythematosus, in such cases treatment should be discontinued immediately. Long-term treatment with adrenocorticosteroids may be necessary. Complete blood counts, L.E. cell preparations, and antinuclear antibody titer determinations are indicated before and periodically during prolonged therapy with hydralazine and if patient develops arthralgia, fever, chest pain, continued malaise or other unexplained signs or symptoms. If the results of these tests are abnormal, treatment should be discontinued.

### Usage in Pregnancy

Animal studies indicate that high doses of hydralazine are teratogenic. Although there is no positive evidence of adverse effects on the human fetus, hydralazine should be used during pregnancy only if the benefit clearly justifies the potential risk to the fetus.

### Precautions

Caution is advised in patients with suspected coronary-artery disease, as it may precipitate angina pectoris or congestive heart failure, and it has been implicated in the production of myocardial infarction. The "hyperdynamic" circulation caused by APRESOLINE may accentuate specific cardiovascular inadequacies, e.g. may increase pulmonary artery pressure in patients with mitral valvular disease. May reduce the pressor responses to epinephrine. Postural hypotension may result. Use with caution in patients with cerebral vascular accidents and in patients with advanced renal damage. Peripheral neuritis has been observed and published evidence suggests an antipyridoxine effect and the addition of pyridoxine to the regimen if symptoms develop. Blood dyscrasias consisting of reduction in hemoglobin and red cell count, leukopenia, agranulocytosis and purpura have been reported. In such cases the drug should be withdrawn. Periodic blood counts are advised during therapy. MAO inhibitors should be used with caution in patients receiving hydralazine. Slow acetylators should probably receive no more than 200 mg of APRESOLINE per day. When a higher dose is contemplated, and, whenever possible, it may be advisable to determine the patient's acetylation phenotype.

### Adverse Reactions

Within the first day or two: headache, palpitations, tachycardia, anorexia, nausea, vomiting, diarrhea, and angina pectoris. They are usually reversible when dosage is reduced or can be prevented or minimized by administering reserpine or a beta-blocker together with hydralazine.  
Less frequent: nasal congestion; flushing; lacrimation; conjunctivitis; peripheral neuritis, evidenced by paresthesias, numbness, and tingling; edema; dizziness; tremors; muscle cramps; psychotic reactions characterized by depression, disorientation, or anxiety; hypersensitivity (including rash, urticaria, pruritus, fever, chills, arthralgia, eosinophilia, and rarely hepatitis); constipation; difficulty in micturition; dyspnea; paralytic ileus; lymphadenopathy; splenomegaly; blood dyscrasias, consisting of reduction in hemoglobin and red cell count, leukopenia, agranulocytosis, thrombocytopenia with or without purpura; hypotension; paradoxical pressor response.

Late Adverse Reactions: Long-term administration at relatively high doses may produce an acute rheumatoid state. When fully developed a syndrome resembling disseminated lupus erythematosus occurs. The frequency of these untoward effects increases with dosage and duration of exposure to the drug and is higher in slow than in fast acetylators. Antinuclear antibody and positive L.E.-cell tests occur.

### Symptoms and Treatment of Overdosage

Symptoms: hypotension, tachycardia, headache, generalized skin flushing, myocardial ischemia and cardiac arrhythmia can develop. Profound shock can occur in severe overdosage.

Treatment: No known specific antidote. Evacuate gastric content, taking adequate precautions against aspiration and for protection of the airway; if general conditions permit, activated charcoal slurry is instilled. These procedures may have to be omitted or carried out after cardiovascular status has been stabilized, since they might precipitate cardiac arrhythmias or increase the depth of shock.

Support of the cardiovascular system is of primary importance. Shock should be treated with volume expanders without resorting to use of vasopressors, if possible.

If a vasopressor is required, a type that is least likely to precipitate or aggravate cardiac arrhythmia should be used, and the E.C.G. should be monitored while they are being administered.

Digitalization may be necessary. Renal function must be monitored and supported as required. No experience has been reported with extracorporeal or peritoneal dialysis.

### Dosage and Administration

Adjust dosage according to individual blood pressure response.

Orally: Initial: 10 mg 4 times daily for the first 2 to 4 days, 25 mg 4 times daily for the remainder of the first week, 50 mg 4 times daily for the second and subsequent weeks of treatment.

Maintenance: adjust dosage to lowest effective levels. Following titration, some patients may be maintained on a twice daily schedule.

Usual maximum daily dose is 200 mg, up to 300 mg daily may be required in some patients. In such cases a lower dosage of APRESOLINE combined with a thiazide, reserpine or both, or with a beta-adrenergic-blocking agent may be considered. When combining therapy, individual titration is essential to ensure that the lowest possible therapeutic dose of each drug is administered.

Parenterally: patients should be hospitalized. Usual dose is 20-40 mg I.M. or by slow I.V. injection or I.V. drip, repeated as necessary. Patients with marked renal damage may require a lower dosage.

For I.V. drip, the ampoule(s) should be added to 5% sorbitol solution, physiological saline or Ringer solution; glucose solution is not suitable for this purpose. Blood pressure levels should be monitored. It may begin to fall within a few minutes after injection, with an average maximal decrease occurring in 10 to 80 minutes. In cases with a previously existing increased intracranial pressure, lowering the blood pressure may increase cerebral ischemia.

Most patients can be transferred to oral APRESOLINE within 24 to 48 hours.

### Availability

Tablets of 10 mg: yellow, uncoated, biconvex, scored, and imprinted "FA" on one side and "CIBA" on the other.

Bottles of 100 and 500.

Tablets of 25 mg: blue, coated, printed "GF" on one side and "CIBA" on the other.

Bottles of 100 and 500.

Tablets of 50 mg: pink, coated, printed "HG" on one side and "CIBA" on the other.

Bottles of 100 and 500.

Ampoules: 1 ml, each containing 20 mg hydralazine hydrochloride, 103.6 mg propylene glycol, 0.65 mg of methyl-p-hydroxybenzoate and 0.35 mg of propyl-p-hydroxybenzoate in water for injection.

Boxes of 10.

Complete Prescribing Information available on request.

### References:

- The Pharmacological Basis of Therapeutics, Sixth Edition, Pages 799-801 - Goodman and Gilman 1980.
- Gifford, R.W., Isolated systolic hypertension in the elderly. *Postgraduate Medicine*, Vol. 71, No. 3, March 1982.
- Finnerty, F.A., M.D., Hypertension in the elderly: Special considerations in treatment. *Postgraduate Medicine*, Vol. 65, No. 5, May 1979.
- Scribaine, A. *Pharmacology of Antihypertensive Drugs*, Methyldopa, page 48, 1980.

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