EDITORIAL

Guidelines and trials

The lead article in this issue is a practice guideline for the use of adjuvant chemotherapy post cystectomy. The guideline was developed by the Cancer Care Ontario (CCO) Practice Guidelines Initiative. The guideline is timely, because the NCIC Clinical Trials Group has just opened a national randomized trial of adjuvant Gemcitabine-cis Platinum in Canada. The guideline emphasizes the current uncertainty in this area.

Evidence based medicine has emerged as a guiding force in medical management. In concert with this, guideline development has become widespread. The methodology and quality varies. At one end of the spectrum, individual clinicians describe their approach. These represent the personal views of the authors, which may be reasonable or extreme.

Evidence based guidelines, which include references to the medical literature for support, are a step up. These reflect a consensus of experts in the field. The CUA guidelines largely fall into this category. The selective use of data in this approach limits the robustness of the conclusions. Without a comprehensive approach to the evidence, there is an increased risk of bias.

The other end of the spectrum is a comprehensive approach to the evidence. The CCO Guidelines process was developed by the Clinical Epidemiology group at McMaster in an attempt to minimize bias. The process begins with a specific question, narrowly framed, on which there is at least a modicum of quality data. This is followed by a comprehensive literature search based on pre-defined terms, and includes a qualitative analysis of every relevant study and systematic review. A group of content experts reviews the data and develops a series of evidence based recommendations. These are then circulated for practitioner feedback, revised, and formulated into a guideline. The resulting guidelines are generally reliable and accurate, reflecting both the published literature and local community standards. The guideline on adjuvant chemotherapy in this issue is a result of this type of intensive deliberation.

There are three pitfalls to this rigorous process.

1. The desire for perfection may mean that the guideline is outdated by the time it is complete. It is labor intensive and slow.
2. Guidelines may fail to change over time. Medical evidence shifts, matures, wobbles, and weaves. An example: there have been 67 Guidelines on Hormone Replacement Therapy published since 1988. These can be presumed to be outdated and misleading in view of the recent publication on the lack of efficacy of HRT from the Women's Health Initiative study. Guideline development, like the myth of Sysyphis, is a process without end.
3. Recommendations may be motherhood. An example was the AUA guidelines on treatment of localized prostate cancer, which concluded that patients should choose between radiation, surgery, and watchful waiting. A guideline, to justify the investment of time and effort, should result in a change in practice by clinicians.

The adjuvant chemotherapy guideline in this issue avoids these pitfalls admirably.

Cystectomy alone is associated with recurrence of cancer in one in three patients. Active agents exist against bladder cancer. The role of adjuvant chemotherapy post cystectomy is an important question to resolve. World wide cooperation has been achieved to implement this trial. There are now two international trials open in Canada testing the role of adjuvant chemotherapy following cystectomy; the p53 trial of MVAC for pTis-pT2 N0 disease, now led by SWOG, and the EORTC led trial referred to earlier for pT2-4, N0-1 disease. These are important studies and must be supported by Canadian urologists. We should aim to have the appropriate one of these trials offered to every patient in Canada who has undergone a radical cystectomy.

The current issue of the journal carries the abstracts from the Quebec Urological Association Meeting. The CJU is pleased to collaborate with the QUA in this regard. The quality of the abstracts is high, and we anticipate that it will be an oustanding meeting.

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