

A primary purpose of this communication is to warn Indian physicians about the dangers of an intra-cardiac catheter that is widely used in the U S, the West and probably much of the world. We do not have data concerning the extent of its use in India. However, it is reasonable to assume that it is widely used, having been imported by those who trained in the West.

The catheter under discussion is the pulmonary artery flow-directed catheter, called the Swan-Ganz catheter after its two inventors. Despite mounting evidence in the U S that the employment of the catheter leads to a large number of excess, unnecessary deaths and that no benefit from its use can be demonstrated, proponents of its use continue to defend their practice in a cult-like manner.

In addition to this specific warning, we intend to discuss two points: first, the enhanced deleterious effect of a harmful medical technology in areas where total resources are limited, and, second, the economic reality that useless or harmful technology drains away support from the useful and helpful medical care of patients.

The Swan-Ganz catheter (SGC) was invented in the late 1960's by two American cardiologists. They developed an approach in which a balloon-tipped catheter could be fed through the right side of the heart and into a branch of the pulmonary artery. Inflation of the balloon fixed the catheter in situ and permitted a variety of measurements. The major advantages were ease of insertion and the ability to measure left-sided "pulmonary capillary pressures" ... so called wedge pressures. In addition, mixed venous blood could be obtained to calculate cardiac output.

It should be emphasised that, to our knowledge and having searched the lit-

erature from 1966 to present, no studies were performed in animals to determine the safety of the catheter! The inventors seemed to assume that the risks of the SGC were approximately

myocardial infarction. After the patients were standardised for severity of disease using a propensity score and multivariate analysis, there was approximately a 50 % increase in mortality in those in whom the SGC was used compared to those with no catheter.

Zion et al collected data on 5,841 patients with acute myocardial infarction, 371 of whom underwent catheterisation. In-hospital mortality was almost four times higher in catheterised patients when

compared with non-catheterised patients.

Blumberg and Binns analysed 290,707 patients with acute myocardial infarction. The standardised mortality rate was approximately twice as high in the catheterised patients when the severity of illness was similar in both groups. Severity of disease was standardised using a propensity score and multivariate analysis.

The most recent large study was performed by a consortium of five university affiliated hospitals. The study included a total of 5,735 critically ill adult patients with pre-specified disease categories (acute myocardial infarction, multi-organ system failure, congestive heart failure, respiratory failure, etc.) hospitalised in intensive care units. Numerous statistical adjustments were made including propensity scoring as well as multivariate analysis to standardise the patient population. Patients receiving the SGC had approximately a 10% higher mortality than matched patients not catheterised.

There is essentially no doubt that the use of the SGC is associated with a highly significant increased mortality. There is some doubt, however, as to the cause of this excess mortality. Confirmed cultists of the Swan-Ganz maintain that the cause is selection bias; more seriously ill patients dominate the catheterised group. Their argument persists despite the fairly rigorous standardisation of patient populations

FLAWED TECHNOLOGY

Death and the Swan-Ganz catheter

it is responsible for unnecessary deaths and has no demonstrable benefit. Why is the Swan-Ganz catheter being promoted?

the same as with simple right-sided cardiac catheterisation. They and subsequent users did not consider the possibility of right-sided endocardial injury which might be produced by a catheter fixed at one end in a branch of the pulmonary artery, whipping the endocardium with each cardiac contraction.

We infer their unawareness of this possibility because there followed a tremendous increase in the use of the catheter in a growing number of patients and in a growing number of disease states.

A 'cult-like atmosphere soon surrounded the use of the catheter. Extravagant statements were made. "The catheter is not important in critical care medicine. The Swan-Ganz catheter is critical care medicine." Needless to say, not only was there failure to determine the safety of the catheter, its alleged benefits were never adequately tested.

Finally, 20-30 years after its introduction and mass use, a series of observations and epidemiologic studies have been published. Although none of them were prospective, randomised, controlled clinical trials, the results have been 'so dramatic that at this time no doubt exists outside the "cult" that the use of the catheter is associated with major numbers of excess and, as will become apparent, unnecessary deaths.

We cite four typical studies.

Gore and co-workers collected 3,263 patients with, usually, complicated

as reported in the studies above.

And now we come to a surprising oversight. Although there are over 100 papers describing complications associated with the use of the catheter, the reported rate of complications in isolated patients is far too small to account for the observed increased mortality overall.

In considering the probable mechanism which explains the large excess mortality rate associated with the use of the catheter, let us go back in the medical literature. Since 1972, there have been published at least seven autopsy series involving hundreds of catheterised patients which demonstrate a common complication of the use of the catheter. That complication is the development of diffuse right-sided endocardial injury occurring along the path occupied by the catheter after its insertion. This might be called the battered endocardium syndrome. The lesions found include diffuse, small haemorrhages, bland mural thromboses, valvular rupture and rupture of the chordae. What is the incidence of these lesions in catheterised patients? Reports vary from 10 % to 80% with a mean of approximately 50 %. As anticipated, the longer the catheter is in place, the larger the percent of patients affected.

The pathologists reporting these lesions did not report — or perhaps failed to realise — that, in general, diffuse right-sided endocardial lesions are not diagnosable during the life of the patient.

Because catheters are usually used in seriously ill patients, the death of such a patient would be attributed to the underlying disease rather than to endocardial injury produced by the catheter.

What are the mechanisms of death produced by diffuse right-sided endocardial injury? Consider, first, that such lesions are arrhythmogenic. In fact, producing endocardial injury is an experimental technique for the study of arrhythmias. Infarction of the injured sites is a rare complication, explaining in large part why these lesions are not

diagnosed in patients with a SGC in place on the intensive care unit.

There is a common physiologic abnormality. Diffuse right-sided endocardial lesions should reduce the diastolic compliance of the right side of the heart. In turn, it has been shown that reduced right-sided compliance leads to reduced left-sided compliance and, in turn, to reduction of cardiac output. Imagine the impact of these abnormalities in a

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patient with a catheter in place who has an underlying acute myocardial infarction or acute pulmonary hypertension.

In any case, catheter-related diffuse right sided endocardial injury would seem to provide a major link between the use of the catheter and the observed, excess mortality in patients in whom the SGC has been placed. (If the reader requires additional convincing, we will be happy to provide a list of the seven studies showing the frequent complication of diffuse right sided endocardial injury resulting from the SGC.)

Now to turn to the special impact of flawed technology on the Third World. Obviously, the resources that are wasted in using a technology with a grossly unfavorable risk:benefit ratio are not available to be spent on measures that improve either longevity or quality of life.

This may be an even more serious problem with regard to India. For example, macro economic policies being advocated by the World Bank may detract from the health needs of the poor of India. Thus, on one hand, the SGC directly squanders resources that can be better used for effective treatment. And on the other hand, general economic policies relating to the World Bank policies may result in less total money available in India for all medical care, both the useful and the useless (or worse, the harmful).

Finally, in closing, it might be pointed out that an appropriate animal study should be done, even at this late date, to document the impact of the SGC on the endocardium, on hemodynamics and on survival. These data could serve as a powerful tool in establishing an accurate risk:benefit ratio for the procedure. For the discussion of details of such a study, interested readers are invited to write to the authors.

SHORT NOTES...

Safe Blood and You, one of the Lifeline Series of publications by the Consumer Guidance Society of India, is a 12 page package of information clarifying doubts that every potential (but hesitating) blood donor may ask, such as who should and should not donate blood, how much and how often? And that most common worry: will I face risks if I donate blood? It also describes how donated blood is stored (ideally, of course) and briefly covers the status of regulation, and quality control.

The booklet is an important contribution towards the safe blood donation programme. The last page contains a list of the names and telephone numbers of blood banks in Mumbai.

Safe Blood and You is available at the Consumer Guidance Society of India, Block J, Azad Maidan, Mahapalika Marg, Opp. Cama hospital, Mumbai 400 001, Tel: 262 1612. Or at the Welfare Organisation for Road Safety and Prevention of Accidents, 10/5 Brady's Flats, Colaba, Mumbai. 400 015, Tel: 284 4848/1616.