How to Report Quality in Pancreatic Cancer Surgery?

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INTRODUCTION

During different time periods different wordings get a special "aire,". Some words are used in a positive sense, but are used so often that they are diffused to include almost everything with a proposed positive value and exclude all that is connected to the bad. Such a word is today "quality" that is used in too many medical papers and journals, but in different settings and meanings. However, it is understandable that the taxpayers/politicians/ hospital managers as well as the patients want to know if, for example, the quality of pancreatic cancer surgery in a certain department or hospital is good, median, or inferior. If possible they would like a simple figure like "quality 7 out of 10" or "quality scored to 3.62 with the X-score". However, quality must be evaluated different if discussed with a backdrop of a surgeon's or hospital's total work load, or if it discussed regarding a single patient. In the same way, "quality" must be put in a time perspective; what was regarded good quality 20 or 30 years ago may not even be acceptable today, and what we today regard as best possible quality hopefully will be laught at by our successors.

All different ways to describe quality in pancreatic surgery (vide infra) will focus on a piece or a few pieces of a picture-puzzle that is called "quality". However, even if a single piece usually will not outline the whole picture, they can give information that is somewhat useful. In most pancreatic surgeons' personal evolution there are abstracts, full papers or just person-to-person information that has made a difference to increase his or her quality in pancreatic cancer surgery. There are good reasons to believe that improvement in quality of surgery consists of several small steps rather than a "magic bullet", and these small attempts should therefore not be disregarded. With this background the aim of this editorial is to discuss the

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meaning of the word "quality" regarding pancreatic cancer surgery both in a more philosophical sense, and how it should be used to progress our surgery further.

The Standard Report

In almost all clinical reports on surgical techniques there are three figures given: mortality, morbidity and long term survival. All these have obviously been of great importance to compare different treatments and to compare different departments and hospitals. The problem is that the figures are not as solid as they look, and they may be – and are – manipulated, wittingly or unwittingly, and give only limited information [1, 2, 3, 4, 5]. One of the assiduous detractors of the surgeons' reports of pancreatic surgery, the Icelandic Birgir Gudjonsson, has recently once again shown how the simple reporting can give a genuine but nonetheless a false picture of the results [6].

Mortality

The meaning of a figure for mortality is to report how many that have died due to the intervention (30-days mortality, mortality before the patient leave the hospital, etc.). However, to be meaningful it should be stated if the mortality is related to the disease for which the intervention was performed, if it was a "surgical complication" (i.e. leakage, bleeding etc.) or "medical" (i.e. heart, kidney or lung failure) and if so. The easiest way to get a zero on the line for mortality is not to operate at all, or - more realistic - to operated only on very fit patients with limited disease. If there is a "0" in the file for mortality, the skill of the operating team is extraordinary and the patients have been selected very well - but it is most probable that some patients that could have benefited from resection have been denied such an operation. This means that a mortality figure must be looked upon the backdrop of the case mix and if it is used 30-day mortality, hospital mortality or something similar. It must be understood that modern intensive care can let patients with severe postoperative complications survive for extremely long period - long periods that are only negative if the patients cannot return to a reasonably good postoperative life.

However, a very short survival might tell more about selection of patients and the skill of treating complications than of the actual surgical skill.

Morbidity

The morbidity is even more difficult to report than mortality due to all too many definitions and limits for reporting. It is obvious that a superficial wound infection treated with peroral antibiotics is very different from a leaking pancreatojejunostomyleading to multiple abscesses treated with percutaneous drains or relaparotomy, but it is still "two complications". This means that it is not only the complications themselves that should be reported but also the "grade" of intervention that had to be performed to help the patient survive. The classification system that is commonly used today is that of Dindo, Demartines and Clavien [7], but there is still no consensus on what should be reported: all complications in every category (difficult to read and interpret), all above classification 3b, etc.

Also, a classification like Dindo's may say something about the preoperative treatment (including the surgical procedure), but has little information if the complications were treated in the right way and no information of the outcome (except death) and no information about possible sequelae to the surgery and its complication – which might be very important for surviving patients. A proxy for complications may also be "time in hospital" and "time in ICU".

I strongly advocate for a procedure-specific registration of complications. For example, leakage from a pancreatoduodenectomy has some similarities with a leakage after a left-sided resection, but the severity is different, the treatment is different, and the prognosis is different. The same goes for abscesses, lung complications and renal failures. To proceed with the surgery it is necessary to go in detail with each procedure and try refinement of each step, and then general complication assessment like POSSUM, total quality score (TQS), etc. [8].

Survival

The report of survival has two sides. It is a "hard value" that is easy to measure, but it may be a too hard value. Long survival is a good requisite for a statement of a good result of a surgery in malignant diseases, but it is not enough. If the patient has lived long but had to be instututionalized or in need of daily total parenteral nutrition and opioids the survival might have more negative than positive features, whereas every good life year added by surgery is a success. The shorter the median survival time, the less important are the exact figures as short survival demands so much pharmacological and nursing facilities, whereas a 5-year survival report much better tells that the patient most probable have been able to live good life for a substantial time.

Being able to work postoperatively is a good proxy to when claiming that the operation had been successful, but such a statement must the also include those who are able to work but want to do something else with their lives or to live as usual retired people due to age do. Ability to work is therefore a good be difficult statement to handle. The old

and simple Karnofsky performance status index was a good indication of the status to complement a figure on survival, but it then must be defined when it should be reported: 6 or 12 month or at another time point to make it possible to compare different hospitals and different managements.

Prerequisites for Guidelines for Measurement of Quality of Pancreatic Cancer Surgery

It is a moral axiom for a centre-of-excellence to be able to report the results of the treatment, not least regarding cost efficacy. Thus, "results" cannot be used in a too narrow, surgical meaning to be accepted and supported outside a very limited number of surgeons.

Simple, Simple: Today it is no secret that most doctors, including pancreatic surgeon, have to deal with administrative and economic tasks and strongly oppose all new registrations not helping the individual patient but are sent into an administrative "cyberspace". Therefore, if it is desirable to report also aspects of surgical quality and get it done in all hospitals and accepted by a majority of the surgeons it is utterly important to make it simple, simple, and simple. If possible all data should be possible to be extracted from already existing administratively gathered data and also be possible to extract by personal with less medical education. All demands for extra registrations will jeopardize the whole reporting.

Surrogate Variables: In many scientific instances it is not possible for theoretical or practical reasons to measure exactly what is demanded, especially in studies where the actual effects can be expected in years far ahead (five- or ten-year survival protecting effects and so on). Then it is accepted to use surrogate variables - indicating but not proving the effects looked for - to learn if the study at all is going in the expected direction. Regarding "quality" this may of course also be possible, but it must be expected that there will be more objections to all surrogates most physicians, administrators, and the public will have opinions whether these variables really reflects what was looked for "quality". For example, if the surgeons score the quality of an item it might be argued that this is only from the surgeons' point of view and not the patients, if long postoperative living is taken as measure of good quality, it might be - there are real reports - that the life during many years was awful due to devasting pain, extreme diahorrea and brittle diabetes, i.e. not reflecting a good result even though the patient lived long. All parameters of "quality" should be thoroughly scrutinized before used in scientific papers.

Validity and Reliability: Of course all measures should measure what it should, and nothing else. In quality measurement there is usually few gold-standards which means that most validations will be made against not validated, older standards. Thus, it will continue to be a large theoretical problem as long as there is no consensus on what the best quality measure of today is. Also, the measurements must be reliable, which means that it will be the same results if the same measurements are done over

and over again, and if the measurement are performed in different places or under different settings. However, it is hard to state that we are there with our measurements today. Moreover, even if there is a consensus of validity and reliability there will still be human differences in how to interpret the results, just as a glass of water can be described as "half full" or "half empty".

Alternative Variables to Describe Quality in Pancreatic Cancer Surgery

There have been many attempts to describe the quality of pancreatic surgery – all of them has reflects at least one type of quality; some from the point of the patient, some from the point of the surgeon, and some from the point of society (tax- or insurance-payers). Here are just some obvious examples:

Time from diagnosis to decision-making and to surgery

Costs effectiveness of preoperative management

Number of lymph node resected

Rates of R0, R1 and R2 operations

Postoperative reevaluation of staging and diagnosis

Need of intensive care unit

Readmittance for in-patient management

Costs of surgery and postoperative in-hospital management

Resection rate population based

Resection rate of patients taken to laparotomy

Percentage of resected patients that get adjuvant therapy

Postoperative quality-of-life

Body weight related to body weight 1 year before the symptoms leading to surgery

Patients' satisfaction with the management

The relatives experiences (spouse, children etc.)

Referring hospital' satisfaction with the cooperation around patients

Outside these – at least partly – measurable items, there are also other factors that in the long run have shown to be of importance for maintenance of a high quality:

Education programs

Basic and clinical research

Participation in multi-institutional programs (including research)

Participation in conferences and creation of guidelines etc.

Discussion of ethical issues regarding the management of patients

Local and national leadership in pancreatology

Futurum

For comparison between department, hospitals, countries and management protocols it is of outmost importance that the same things are compared. Then it is needed:

- definitions of each variable
- consensus on what to report and the importance of the variable reported
- standardization of what should be reported
- at least some hints on cut-off levels below which quality is inferior

However, there is still one difficulty left when doing comparisons on bases of these "quality measurement consensus" – there will probably be a selection bias on who is reporting in an "official" way. That means that all published results and any meta-analysis of them will be skewed against the centers-of-excellence. If this is good or bad may be discussed, but obviously the results available from the literature will come from centers and surgeons that are above the median – if they are under they will not bother to publish (or are not allowed by the hospital owner), and if they despite that try to publish not any recognized journal will take the report.

I would like to emphasize that it is still "allowed" to report mortality, morbidity, survival and hospital stay regarding pancreatic cancer surgery. However, in the centers-of-excellence these figures are of less importance than before as they to such a high degree is dependent on case-mix. Moreover, patient management today is complex both regarding pre-, per-, and postoperative management, economical factors and organization.

Most probable an international consensus on how to report quality of cancer surgery – just as other type of complex surgery – is the only way to compare results of different sites. A way to be more useful to improve the treatment of the individual patient, however, is to proceed to procedure-specific measurements, especially complication measurements.

Conflict of Interest

The authors have no potential conflict of interest.

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