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Quality Control in Pancreatic Surgery: Just how Easy is it?

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Surgery for pancreatic cancers is technically demanding, and associated with significant morbidity. Globally, considerable variations exist in resection criteria and techniques. Assessing the quality of surgery (and therefore the care which patients receive) is a cornerstone of optimizing health-care delivery. But just how easy is it to determine appropriate metrics of good surgery?

The acid test for any surgeon is their mortality rate. For pancreatic resections, there has been a marked reduction in the post-operative mortality across the last four decades: from 5% before 1980 to 2.9% from 2000 onwards (range of 0-9%) [1]. It would appear that mortality following pancreatic resection should certainly be no higher than 5% and ideally around 3%. This easily-measured metric would seem an ideal starting point for centre and surgeon comparisons. Morbidity following pancreatic resection remains relatively high at 30 to 50% [2-20]. The development of pancreatic fistulae after pancreaticoduodenectomy is a major determinant of morbidity. Fistula rates vary in the literature, but reported incidences are from 2 to 20% [2-10]. Clear definitions of what constitutes a pancreatic fistula, along with severity grading have been published [11] and this allows for pancreatic fistula rates to possibly be used as an index of performance.

Standardisation of results-reporting is essential to use morbidity and mortality as quality indices. This requires risk stratification against the background population and standard mortality benchmarks (for example 30, 60, 90-day mortality or in-hospital mortality) along with standardised reporting/grading of complications [12]. The wide variation in reported fistula rates serves to highlight the work required in standardising and defining these parameters to enable their use as quality indices. It is clear that complex surgical procedures performed in high-volume centers have reduced preoperative morbidity and mortality when compared with 'low-volume' centers [13-15]. The centralization of workload to designated hospitals facilitates the focusing of resources along with a reduction in preoperative morbidity and overall cost of treatment. [16-18]. These potential benefits must be offset against a strong patient preference for local care; up to 20% of patients would be willing to accept a 6-fold increase in their post-operative mortality, if it would enable them to have their operations locally rather than travel to a regional centre [19].

The inverse relationship between hospital volume and mortality was first described in 1979 [20] and is most marked for high-risk procedures such as pancreaticoduodenectomy [15]. A detailed systematic review of hospital volume and mortality for pancreatic resection undertaken by Van Heek et al. [21] found that mortality rates were as high as 16.5% in hospitals undertaking less than 5 pancreatic resections annually, compared to 3.5% in those doing 24 or more [21,22]. However, whilst a very high volume centre is easy to differentiate from a very low volume centre; there is considerable ambiguity between these extremes. Would there be a significant difference in expertise between a hospital undertaking 50 pancreatic resections per year versus another undertaking 35? In addition, although overall hospital volume has been shown to impact favorably on outcome, individual surgeon experience has also been found to be important. A recent report suggests that experienced surgeons continue to obtain favorable results irrespective of annual volume [23]. This may be an important consideration for experienced pancreatic surgeons who continue to operate in low-volume centers.

Pathology could also be used to assess quality of resection surgery; namely resection margin and lymph node status. The median cross-study survival for R1 resections is 10.3 months versus 20.3 months for R0 margins [1]; although some studies have failed to demonstrate a statistically significant survival benefit [24-28]. R1 margins do not appear to influence survival as strongly as lymph node status, perineural or micromeshes invasion [1]. A recent review of 4 studies incorporating 875 patients did not identify positive resection margins as a significant factor for survival [29] and ESPC-1 data also found R1 patients to have only a marginally worse survival than R0 [30].

This paradox is explained by the wide variation in the pathological processing and reporting of pancreatic specimens [31]. These discrepancies in resection margin assessment obfuscate comparison of multinational studies and suggests under-reporting of positive margins by pathologists [32,33]. Furthermore, positive resection margins may impact on survival by acting as an indicator of biological aggressiveness rather than being than being a technical factor which could be influenced by the operating surgeon [34]. ESPAC-1 data reported an R1 margin rate of 18%, however, for the reasons discussed greater variation than this may exist between centers due to variations in specimen handling and reporting. Resection margins would require further standardization before they could be used as an index of surgical quality.

A systematic review of 51 studies found that lymph node status was a predictor of survival on either univariate or multivariate analysis [1]. The median cross-study survival for lymph node negative patients (N0) was 25 months and 13.6 months for lymph node positive patients (N1). Lymph node yield following pancreaticoduodenectomy is an easily measured metric which might be used to determine quality of surgical resection.

Whilst lymph node status may alter prognosis; it is far from clear whether radical lymph node dissection would alter outcomes for patients. There have been four randomized controlled studies examining extended lymphadenectomy during pancreaticoduodenectomy which found ad no survival benefit [35-38] and a trend towards increased morbidity [39].There is no data to suggest how many lymph nodes are adequate for a pancreatic resection. Pawlik et al. [40] found that only 0.3% of patients would achieve a survival advantage following an extended lymphadenectomy. A further consideration is that

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patients who have extensive lymph node involvement would have a high probability of concurrent hepatic micrometastases, thereby precluding them from the potential benefit of radical resections.

Morbidity, mortality, volume of work, extent of lymphadenectomy and R0/R1 resection rates would appear to be obvious candidates as metrics of quality of pancreatic cancer surgery. However, these metrics are subject to considerable variation and interpretation. In order to improve the quality of pancreatic surgery, we must be sure what we are measuring (and asking pancreatic surgeons to adhere to) truly reflects how well that surgery is being undertaken; and impacts favorably on long-term outcomes. Equally we must be careful not to identify wide-spread yet sub-optimal surgical methods and accept this as the standard of care.

Attempting to define standard metrics will improve oncological standards in HPB surgery and inevitably improve patient care. The collation of accurate multi-centre data is essential to define these metrics and enable meaningful bench-mark figures to be set. Whilst many of the data items are currently already collected in a variety of hospital departments the collation of the data may prove difficult due to the different databases used. It seems likely that in the interim the collection and collation and meaningful data will rely on clinician engagement and national audits.

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