

Volume of procedures and risk of recurrence after repair of groin hernia: national register study

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ABSTRACT

Objective To determine whether the association between volume and outcome found in major surgery also holds true for a minor operation.

Design Review of outcomes after hernia surgery in Sweden.

Setting Surgical units registered with the Swedish hernia register, which in 2004 covered about 95% of all hernia operations in Sweden.

Participants 86 409 patients over 15 years, who underwent 96 601 unilateral or bilateral groin hernia repairs (94 077 inguinal and 2524 femoral) in 1996-2004 at the participating surgical units.

Main outcome measure Re-operation for recurrence.

Results There was a significantly higher rate of re-operation in surgeons who carried out 1-5 repairs a year than in surgeons who carried out more repairs. There was no association between outcome and further increases in volume. Although about half of surgeons in Sweden who repair hernias are low volume operators, they performed only 8.4% of all repairs.

Conclusions Sweden's numerous low volume hernia surgeons perform such a small proportion of all operations that the impact of their inferior results on the nationwide re-operation rate is minimal. Volume indicates an approximate minimum value for the number of hernia repairs a surgeon should do each year but the outcome in surgeons who carry out more than that number disqualifies volume as an indicator of proficiency.

INTRODUCTION

Studies on the relation between volume and outcome use one single indisputable end point—that is, mortality.¹⁻⁴ Though the evidence on which the relation between volume and outcome is based now seems less firm than originally thought,⁵ the use of mortality as the single indicator of quality of care also limits studies to major surgery with a calculable risk to life. To determine whether or not their results might be extrapolated to minor surgery, we considered groin hernia surgery as a suitable example. It has one dominant end point—that is, recurrence⁶—which can reliably be assessed and occurs often enough to serve as a measure for success. We studied the relation between the number of repairs carried out by surgeons and the incidence of re-operation

in nearly 100 000 hernia repairs prospectively recorded in a hernia register in 1996-2004.

METHODS

Data source

The Swedish hernia register,⁷ which contains detailed information on more than 100 000 groin hernia repairs, provided the data. In 2004 the register covered about 95% of all hernia operations in Sweden. The register data is externally reviewed on an annual basis, and participating units report 98% of all the groin hernia repairs they perform.⁸ The sample comprised all patients aged over 15 years who underwent groin hernia repair in 1996-2004 at surgical units participating in the register. In the Swedish health system the patient is usually not free to choose either surgeon or hospital and there is no guaranteed continuity of care. In the statistical analysis we adjusted for emergency and re-operations. A complete description of the register's recorded data and validity checks is published elsewhere.^{8,9}

The register has permission to use the personal identification number by which every Swedish citizen can be identified. Thus, patients can be followed annually to link recurrent hernia repair, mostly occurring within five years, to previous surgery at other participating units.¹⁰

Surgeon volume

We defined volume as the number of operations for which a particular surgeon was legally responsible. As surgeons changed volume over the years we assessed volume every year and assigned the surgeons annually to one of four categories: 1-5, 6-25, 26-50, and >50 hernia repairs a year. We used the resulting distribution of annual classifications as distribution of surgeon volume. For the study of a possible linear relation between volume and outcome we divided the series into nine groups: 1-5, 6-10, 11-15, 16-20, 21-25, 26-35, 36-50, 51-75, and >75 repairs.

Hospital and surgical methods

We classified hospitals as university and other teaching hospitals, medium sized hospitals with a 24 hour emergency service, and smaller units for day surgery only. We divided methods of operation into five

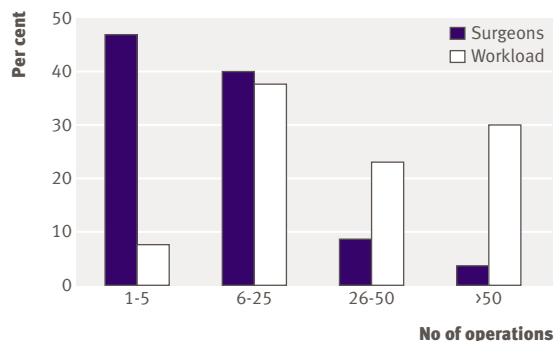


Fig 1 | Four categories of surgeons according to number of hernia repairs carried out

groups: Lichtenstein, Shouldice, plug methods, other open methods, and laparoscopy methods.

Statistics

We used SPSS version 12.0.1 (Chicago, IL) for all analyses. All P values given are two tailed. We used χ^2 to examine differences between groups and estimated relative risks of re-operation with Cox’s proportional hazards regression model¹¹ adjusted for both emergency operation and earlier repair of the same groin in multivariate Cox’s regression analysis. Adjustments were also made for type of unit and surgeons’ annual volume, when necessary. For the Cox’s analysis re-operation was defined as a hernia repair in the same groin as an earlier repair documented in the hernia register.

RESULTS

Surgeon volume and workload

Figure 1 shows the number of surgeons in the four volume categories. The columns are based on the numbers of annual classifications in the four categories, expressed as percentages of the total number of classifications during the study period (7330). The figure also shows the contribution to the total workload—that is, the surgeons’ number of repairs expressed as percentages of the total number of hernia repairs (96 601).

The category of surgeons with the lowest volume (1-5 operations) might be large in numbers, with 3471 of the total number of 7330 annual classifications—that is, 47.4%—but they performed only 8078 of the 96 601 repairs—that is, 8.4%. By contrast, the category with the highest volume (>50 operations) accounted for 300 of the 7330 classifications—that is, 4.1%—but this group performed 28 895 of the 96 601 repairs (29.9%).

Surgeon volume and type of hospital

There were marked differences in surgeon volume according to the three categories of hospital (fig 2). Occasional operators dominated in the university clinics, with 815 of 1184 classifications (68.8%) in the category of 1-5 operations. The corresponding figures for the medium and smaller clinics were 2241 out of 4916 (45.6%) and 415 out of 1230 (33.7%), respectively. By contrast, there were more frequent operators (>50 operations) in the smaller clinics, with 177 out of 1230

classifications (14.4%) compared with 32 out of 1184 (2.7%) in university clinics and 91 out of 4916 (1.9%) in the medium sized clinics. There was a similar difference, although less marked, in the category of 26-50 operations. In the smaller units 14.3% of the classifications belong to that category compared with 4.2% and 8.6%, respectively, in the university and medium sized clinics.

In 1996-2005, 10 310 of the 96 601 hernia repairs (10.7%) were performed in university and other teaching hospitals, 57.0% in the medium sized hospitals, and 32.3% in the smaller units.

Surgeon volume and method of operation

We compared the operative methods used by low volume surgeons (1-5 operations) with those used by surgeons who carried out more than five repairs a year. The Lichtenstein repair dominated in both groups, with more in the low volume (1-5) group than in the high volume (>5) group: 58.7% (4738/8078) v 54.9% (48 576/88 523). The Shouldice method was used in 10.5% and 10.6% of all operations in the two compared groups, respectively, while the use of other methods with their higher re-operation rates showed some differences. The low volume operators used other open methods (18.0% v 8.6%) more often and plug methods (9.2% v 14.6%) and laparoscopy (3.7% v 11.5%) less often.

Results in relation to type of hospital

Table 1 shows the relative risk of re-operation in the three types of hospital after adjustment for volume. When we used the risk of re-operation in the smaller units as a reference, both the university and the medium sized hospitals scored better than the reference with relative risks of 0.87 (P<0.05) and 0.88 (P<0.01), respectively.

Results in relation to volume

Table 2 gives the relative risk in the nine volume groups, with the ninth group (>75 operations) as the reference, with adjustment for the type of hospital. Low volume surgery (1-5) was associated with a significantly higher relative risk (1.20, 95% confidence interval 1.01 to 1.42). The effect of low volume was no longer apparent in the 6-10 range, where the relative risk approaches unity, and this is followed by a significant dip corresponding to the 11-15 operation range

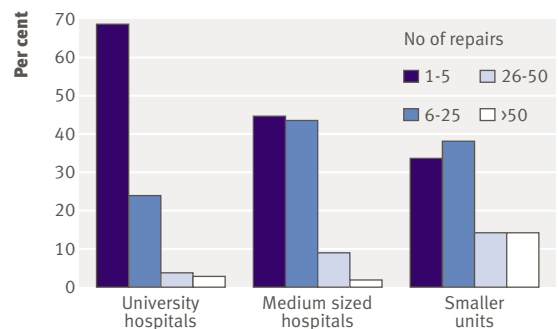


Fig 2 | Groin hernia surgeons classified according to annual volume at three types of hospital.

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Table 1 | Relative risk of re-operation, relative to type of unit

Type of unit	No of operations	RR (95% CI)	P value
University hospitals	10 310	0.87 (0.751 to 0.998)	0.047
Medium sized hospitals	55 041	0.88 (0.795 to 0.964)	0.007
Smaller units	31 250	1 (reference*)	—

*Multivariate analysis according to Cox's proportional hazards model with smaller units as reference and adjusted for emergency repair, recurrent repair, and surgeons' annual volume.

($P > 0.01$). After that the relative risk goes up again and is hovering around unity.

DISCUSSION

Main findings

In this study of the relation between volume and outcome in hernia surgery in Sweden we found a significantly higher risk of re-operation when the surgeon carried out less than six operations annually. In those who did 6-10 operations the relative risk returned to unity—that is, the value of the reference group (>75 operations), after which it showed a significant dip, followed by a gradual return to the reference group's value. We also found that although about half of Sweden's hernia surgeons do low numbers of repairs (1-5 annually), their contribution to the total workload is small. Consequently, the impact of their inferior results on the nationwide re-operation rate is minimal.

Strengths and weaknesses

The study population is large, nearly completely covered, and all data were prospectively recorded. As there were so many low volume surgeons (47.4%), the combined number of their few individual operations was large enough (8078, 8.4%) for us to study the effect of low volume on outcome. We avoided possible bias caused by changes in surgeon volume by annual reclassification. Finally, the Swedish health system usually does not allow for a free choice of surgeon, which simplifies the study of the association. Low volume might lead to poor outcome and not the other way round.

As our yardstick for outcome we used the re-operation rate. For obvious reasons register data cannot give information about the exact recurrence rate. Validation studies have shown the recurrence rate to exceed the re-operation rate by a factor of 1.7 to 2.3, depending on definition of recurrence and method of follow-up.^{6,12} Experience so far has failed to give any indication of covariation between the recurrence rate/re-operation rate quotient and study variables. Our conclusions regarding the association are based on the assumption of absence of such covariation.

The inferior results of the low volume surgeons were not linked to the type of hospital. Indeed, the university clinics and the medium sized hospitals had significantly higher proportions of low volume operators than the smaller units, but despite this they had better results. Neither could the inferior results of the low volume surgeons be ascribed to a difference in operative method. Lichtenstein, the method which in Sweden had the lowest re-operation rate,¹³ was used in a larger

proportion of operations in the 1-5 operation group than in the >5 operations group. Moreover, the methods associated with higher recurrence rates were used rather sparingly in both groups and might be assumed to cancel each other out.

Relation to major surgery

The behaviour of the association between volume and outcome in hernia surgery differed from what has been found in major surgery. When Birkmeyer et al assessed surgeon volume as a continuous variable, they found volume to be inversely related to mortality in all of the eight complex surgical procedures studied.¹ In groin hernia surgery we found no such consistent effect of volume on outcome. Instead, there was a significant decrease in the relative risk when the surgeon carried out more than five operations annually. The rapid disappearance of the effect of low volume in hernia repair compared with major surgery can be explained by the difference in technical difficulty. Fewer cases are needed to learn a simple technique than a complex one and the same probably holds true for the respective volumes needed to maintain the acquired skills. Thus, in a volume/outcome study of hernia surgery, where the desirable minimum volume is low, most data are likely to stem from operations performed by surgeons with volumes above the desirable minimum while the opposite might be the case in highly complex procedures. In a groin hernia study the effect of increasing volume might therefore quite soon be expected to decrease or disappear; in studies of complex procedures it won't.

The observation of a sharp decrease at five operations annually should not be accepted at face value. That number was chosen in an effort to construct nine more or less comparable volume groups. Instead, the observation suggests that there might be a suitable minimum for annual volume somewhere in the single digits. A similar rapid disappearance of the effect of the surgeon's increased volume has been noted in another less complex, although risky, operation—for example, carotid endarterectomy, a form of surgery with a strong relation between hospital volume and outcome.¹⁴ In

Table 2 | Relative risk of re-operation, relative to surgeon's annual volume of hernia repairs per year

Repairs	No of operations	RR (95% CI)	P value
1-5	8 078	1.20 (1.01 to 1.42)	0.035
6-10	9 506	1.01 (0.86 to 1.19)	0.905
11-15	10 569	0.80 (0.68 to 0.94)	0.008
16-20	8 911	0.92 (0.77 to 1.08)	0.298
21-25	8 147	0.98 (0.83 to 1.15)	0.795
26-35	11 781	0.87 (0.77 to 1.04)	0.155
36-50	10 714	0.91 (0.78 to 1.06)	0.208
51-75	8 077	1.04 (0.89 to 1.22)	0.601
>75	20 818	1 (reference*)	—

*Multivariate analysis according to Cox's proportional hazards model with volume >75 repairs as reference and adjusted for emergency repair, recurrent repair, and type of unit.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Volume/outcome studies use mortality as their end point and so tend to be restricted to major surgery

Whether their results can be extrapolated to minor surgery remains unclear

WHAT THIS STUDY ADDS

About half of Sweden's hernia surgeons are low volume operators with a re-operation rate that is significantly higher than that of the other half

Low volume operators performed less than 10% of all repairs and their impact on the re-operation rate was minimal

Though volume indicated a minimum value for experience, outcomes above that value disqualified volume as an indicator of the surgeon's proficiency in hernia repair

surgeons who performed three or more such operations in two years, increased volume was not associated with better outcomes.¹⁵

Impact of low volume hernia surgery

Almost half of Sweden's hernia surgeons (47.4%) were low volume operators (1-5 operations a year) and their re-operation rate (without correction for type of unit) was 30% higher than that of the other half. But, as low volume surgeons by definition perform few operations, their contribution to the total workload was small (8.4%). The cumulative relative risk after five years was 3.8%. The elimination of low volume surgery could reduce the overall relative risk from 3.8% to 3.7%, a negligible effect compared with, for example, the elimination of inferior repair methods.^{16,17} Priority should therefore be given to the general adoption of the most effective methods.

The disappearance of the low volume effect in the 6-10 operation range did not show as the expected gradual levelling off in relative risk. Instead, there was a significant dip, followed by a gradual rise. Whatever the correct explanation might be, the dip with the subsequent rise of the relative risk is clearly at variance with a relation between volume and outcome. It shows that at a relatively low level this relation has played out its role.

Experience has always been considered as one of the factors that determine the quality of surgical care. There are solid grounds for this time honoured premise on which surgical training is based. Even in surgical trials the experience of participating surgeons before the trial might leave its mark on the results.^{18,19} In our study, volume could indicate an approximate minimum value for experience in hernia surgery. Yet, the outcome's erratic reaction to further increases in volume supports the view that, whatever its merits in assessing the impact of hospital characteristics,²⁰⁻²² volume is not a good indicator for a surgeon's success in hernia repair. Above a certain minimum value, qualities other than experience seem to take over as sources of variation in outcome.

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