

National Register Study of Operating Time and Outcome in Hernia Repair

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Objectives: To examine the relationship between operating time and reoperation for recurrence and other complications in groin hernia repairs.

Design: Observational population-based register study.

Setting: Data from the nationwide Swedish Hernia Register, which prospectively collects data from almost all groin hernia repairs performed in Sweden.

Patients: There were 123 917 primary groin hernia repairs recorded in the Swedish Hernia Register from January 1, 1998, through December 31, 2007.

Main Outcome Measures: Relative risk of reoperation for recurrence and odds ratios for postoperative complications in 4 operating time groups.

Results: The relative risk of reoperation for recurrence of all patients operated on in less than 36 minutes was 26% higher than that of all patients with an operating time of more than 66 minutes (1.26; 95% CI, 1.11-1.43). Because the Lichtenstein procedure is the standard procedure in Sweden today, its results were also analyzed separately. In this homogeneous group, the difference was even more striking with an increased relative risk of 45% (1.45; 95% CI, 1.21-1.75). The odds ratio for infection and other postoperative complications increased with increasing operating time.

Conclusion: A significant decrease in reoperation for recurrence with increasing operating time exhorts the hernia surgeon to avoid speed and to maintain thoroughness throughout the procedure.

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LITTLE IS KNOWN ABOUT THE relationship between operating time (OT) and outcome of minor surgery, but groin hernia surgery—which has 1 predominant, dichotomous, easily assessable end point (ie, recurrence)—might give an indication. In the

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present study, we analyzed the relationship between OT and reoperation for recurrence as well as OT's relationship to postoperative complications in 123 917 primary groin hernia repairs recorded in the Swedish Hernia Register (SHR) from January 1, 1998, through December 31, 2007.

METHODS

DATA SOURCE

The SHR is a national register that monitors nearly 100% of all surgical units performing groin hernia repairs in Sweden. Data regarding all groin hernia operations on patients aged 15 years or older are prospectively documented according

to a protocol recorded by the surgeon immediately after the operation. The large study population and almost complete coverage of every inguinal and femoral hernia operation performed in an adult in Sweden imply that SHR constitutes an unselected and unbiased database and act to minimize the risk of random error.

All registered data are processed at the register center once a year after extensive data controls. Registered hernia repairs are followed up from date of surgery until a reported date of reoperation on the operated side. Repairs without observed reoperation continue to be followed up until date of death.

Each year, an external reviewer compares data sent to the register center with a sample of operative records, anesthetic notes, and patient files from 10% of randomly selected aligned units to check the validity of the data. The register has been found to include 98% of eligible operations.¹

Thanks to the national person-number system, patients can be followed up annually to adjust life tables for deaths and to link recurrent hernia repair to previous surgery anywhere in Sweden.² There is no obligatory follow-up, but all complications that come to the knowledge of the surgical departments within 30 days of the operation have to be reported. Because the SHR lists only hernia patients who undergo surgery, its data on recurrence are limited to patients who undergo reoperation. A complete description of the SHR's recorded data and validity controls has been published previously.^{3,4}

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The present study includes all registered primary groin hernia repairs performed in Sweden from January 1, 1998, through December 31, 2007. Exclusion criteria were recurrent hernia and patient age younger than 15 years.

DEFINITIONS

Groin hernias include all inguinal and femoral hernias. Reoperation of recurrence is defined as any kind of hernia repair in a groin previously operated on for a hernia when the patient was aged 15 years or older.

OPERATING TIME

Operating time was measured as the exact time between the first incision to the final stitch (skin to skin) and is registered by the surgeon or the staff in the operating room in direct connection with surgery. The OT was grouped into approximate quartiles: less than 36 minutes, 36 to 50 minutes, 51 to 66 minutes, and more than 66 minutes. Annual validated spot checks showed the reported OT data to correspond closely with similar data in the independently completed anesthesia notes.¹ Therefore, the data were considered reliable enough to serve as a basis for a division of all operations into 4 OT groups. For the study of a possible linear relationship between OT and outcome, a division into a larger number of OT groups was considered suitable. For that purpose, we divided the series into 8 roughly equal groups.

Bilateral hernias are registered as 2 separate procedures. A separate OT was recorded for the respective side.

METHODS OF REPAIR

Methods of repair were grouped into (1) open sutured repair, (2) open mesh repair (values are given for all open mesh repairs as well as for Lichtenstein only), (3) open preperitoneal mesh repair, (4) laparoscopic mesh repair (eg, transabdominal preperitoneal or total extraperitoneal repair), and (5) plug methods. Previous studies on OT have shown substantial differences between the various methods. To avoid this source of variation, comparisons were made of all techniques as well as of 1 technique only, that is, Lichtenstein, which at present is the dominating operative method in Sweden and counts for 65% of all repairs.

ALLOCATION OF PATIENTS TO SURGEONS

In the Swedish National Health Service hospitals where the bulk of the hernia surgery is performed, the allocation of patients to the various surgeons is rarely influenced by their reputation for speed or volume. The patient is usually not free to choose either surgeon or hospital, and there is no guaranteed continuity of care.

POSTOPERATIVE COMPLICATIONS WITHIN 30 DAYS OF SURGERY

Infection was considered present when local signs of inflammation, purulent secretion, and/or positive wound culture were observed. Urine retention needing catheterization, hematoma, severe pain, and other complications (eg, seroma or ischemic orchitis) were also considered postoperative complications.

SURGEON VOLUME

All surgeons were divided into 4 groups according to their annual number of operations as described previously⁵: 1 to 5, 6 to 25, 26 to 50, and more than 50 hernia repairs per year. Be-

cause volume varied over the years, all surgeons were reclassified every year.

STATISTICS

All statistical analyses were performed in the publicly available software R (version 2.7.2; R Foundation for Statistical Computing, Vienna, Austria; <http://www.r-project.org>). $P < .05$ was considered statistically significant, and all P values given are 2-tailed. Hazard ratios were calculated using the multivariate Cox proportional hazards regression model, and odds ratios were calculated using logistic regression.⁶

ETHICS

All patients included in the SHR have given their informed consent. The research ethic committee of Umeå University, Sweden, approved the study.

RESULTS

PATIENT CHARACTERISTICS AND EXCLUSIONS

A total of 124 325 primary groin hernia repairs were performed from January 1, 1998, through December 31, 2007. For 310 operations (0.25%), OT had not been reported. Those cases were excluded. An OT of less than 10 minutes or more than 300 minutes was considered dubious, which led to the exclusion of another 98 repairs (0.08%). The remaining 123 917 operations were included in the analyses. The median duration of operation was 50 minutes. Patient characteristics for the 4 OT groups are summarized in **Table 1**.

OT AND RELATIVE RISK OF REOPERATION

As seen in **Table 2**, which comprises the results of all 123 917 operations, reoperation for recurrence was performed in 2677 patients (2.16%). The relative risk (RR) for reoperation increased with decreasing OT. Patients operated on in less than 36 minutes had a significantly increased RR of 1.26 (95% CI, 1.11-1.43) compared with the reference group, which had an OT of more than 66 minutes. To exclude the possibility that this finding reflects a correlation between the various methods' mean OT and their RR, a repeat comparison was restricted to operations according to Lichtenstein. In this comparison, the differences were even more marked, with an RR of 1.45 (95% CI, 1.21-1.75) for reoperation of the group with the lowest OT in its comparison with the reference (Table 2).

The relationship between RR and OT is illustrated in **Figure 1**, where OT greater than 80 minutes serves as the reference. Figure 1 shows OT assessed as a continuous variable, and the transition from a significant to a non-significant RR for reoperation for recurrence occurs after approximately 50 minutes.

OT AND VOLUME

Figure 2 shows the relationship between volume and OT in all 123 917 operations. In the lowest volume group (1-5 repairs per year), the percentage of operations lasting more

Table 1. Patient Characteristics Divided Into 4 Operating Time Groups

Characteristic	No. (%) of Patients, by Operating Time, min ^a				Total
	<36	36-50	51-66	>66	
Total	33 740 (27.2)	32 984 (26.6)	26 689 (21.5)	30 504 (24.6)	123 917 (99.9)
Sex					
Male	30 294 (26.6)	30 291 (26.6)	24 795 (21.7)	28 677 (25.1)	114 057 (100.0)
Female	3446 (34.9)	2693 (27.3)	1894 (19.2)	1827 (18.5)	9860 (99.9)
Age, y					
<60	17 800 (29.4)	16 242 (26.8)	12 730 (21.0)	13 731 (22.7)	60 503 (99.9)
≥60	15 940 (25.1)	16 742 (26.4)	13 959 (22.0)	16 773 (26.4)	63 414 (99.9)
Surgeon volume					
1-5	1347 (12.0)	2778 (24.7)	2929 (26.1)	4181 (37.2)	11 235 (100.0)
6-25	7211 (15.3)	12 148 (25.8)	12 157 (25.8)	15 602 (33.1)	47 118 (100.0)
26-50	5764 (21.3)	7723 (28.6)	6476 (24.0)	7069 (26.2)	27 032 (100.1)
>50	18 944 (52.6)	9691 (26.9)	4537 (12.6)	2822 (7.8)	35 944 (99.9)
Methods of repair					
Open sutured	4509 (33.2)	3864 (28.5)	2701 (19.9)	2505 (18.5)	13 579 (100.1)
Open mesh, all	15 503 (19.2)	21 014 (26.0)	19 820 (24.5)	24 417 (30.2)	80 754 (99.9)
Lichtenstein	13 344 (18.5)	18 639 (25.8)	18 039 (24.9)	22 301 (30.8)	72 323 (100.0)
Open preperitoneal	377 (32.1)	288 (24.6)	224 (19.1)	284 (24.2)	1173 (100.0)
Laparoscopic mesh	4185 (46.7)	2397 (26.7)	1341 (15.0)	1044 (11.6)	8967 (100.0)
Plug	7398 (48.9)	4256 (28.1)	2020 (13.3)	1466 (9.7)	15 140 (100.0)
Anatomy					
Direct	13 319 (31.9)	11 796 (28.2)	8578 (20.5)	8069 (19.3)	41 762 (99.9)
Indirect	17 749 (25.9)	18 003 (26.3)	15 020 (21.9)	17 789 (25.9)	68 561 (100.0)
Combined	1633 (16.9)	2227 (23.1)	2301 (23.9)	3479 (36.1)	9640 (100.0)
Femoral	790 (25.8)	735 (24.0)	599 (19.6)	935 (30.6)	3059 (100.0)

^aWith the exception of the Sex and Age categories, all subtotals within each category do not sum to the total for the column because of missing data.

Table 2. Relative Risk (RR) of Reoperation for Recurrence in the 4 Operating-Time Groups^a

Operation Time, min	No. of Patients	Reoperation, No. (%)	RR (95% CI)	P Value
All methods				
<36	33 740	934 (2.8)	1.26 (1.11-1.43)	<.001
36-50	32 984	699 (2.1)	1.08 (0.95-1.22)	.22
51-66	26 689	533 (2.0)	1.10 (0.97-1.25)	.14
>66	30 504	511 (1.7)	1.00 [Reference]	...
Lichtenstein				
<36	13 344	264 (2.0)	1.45 (1.21-1.75)	<.001
36-50	18 639	312 (1.7)	1.26 (1.06-1.49)	.007
51-66	18 039	250 (1.4)	1.09 (0.91-1.29)	.36
>66	22 301	275 (1.2)	1.00 [Reference]	...

^aMultivariate analysis according to Cox proportional hazards model, adjusted for surgeon's annual volume, method of repair, emergency repair, age, sex, type of surgical clinic, and hernia anatomy.

than 66 minutes is 3 times as high as that of operations lasting less than 36 minutes. The highest volume group (>50 operations per year) shows the exact opposite, that is, 8 times as many operations lasting less than 36 minutes than repairs lasting more than 66 minutes. The differences between the 2 medium-volume groups are less extreme but point in the same direction. Thus, an increase in volume is linked to a decrease in OT.

OT AND METHODS OF REPAIR

As seen in Table 1, differences in OT were found between the various methods of repair. The data suggest that the plug and laparoscopic methods can be performed faster than the other methods. The Lichtenstein method seems to be a more time-consuming procedure than the others.

EFFECT OF OT ON RR FOR REOPERATION IN SUBGROUPS

Comparison of the sexes showed that women run a higher risk of reoperation than men. The difference is small and nonsignificant after operations lasting less than 36 minutes, but it is significant in the 3 remaining groups of lengthier operations. Old age seemed to be of minor importance. Patients aged 60 years or older had a significantly higher RR for reoperation only in the OT bracket of less than 36 minutes (**Table 3**).

OT AND COMPLICATIONS

Table 4 shows that the odds ratio for postoperative complications increases with increasing OT. With OT greater

than 66 minutes as a reference, the odds ratio for complication is 0.72 (95% CI, 0.67-0.77) if the operation lasts less than 36 minutes. The increase of the odds ratio for infection with increasing OT is even more marked. Again with OT greater than 66 minutes as a reference, the odds ratio for infection is reduced to 0.54 (95% CI, 0.46-0.63) if the operation lasts less than 36 minutes. In the present series, 87.93% of all infections were considered superficial, and only 2.72% of the patients with infection had to undergo reoperation.

COMMENT

The present study found that in Swedish hernia surgery, the RR of reoperation showed a significant and substantial decrease with increasing length of OT. This negative association appeared in the combined data of all operative methods as well as in those of the Lichtenstein procedure when studied separately. As for the accuracy of the notes on OT, annual spot checks compared the data reported by the surgeon with the anesthesia notes.¹ Because a surgeon's annual volume may vary, it probably is a rather crude measure for his or her expertise. Therefore, we preferred a division into 4 large groups.

The strengths of the present study are the large study population, the almost complete coverage of every inguinal and femoral hernia operation performed in an adult in Sweden, as well as the fact that the data were prospectively collected. The SHR constitutes an unselected and unbiased database that reflects everyday routine surgical practice and repairs performed by medical practitioners whose professional skills span from relatively inexperienced to expert at hernia surgery.

The study's main limitation is the use of reoperation as the end point because register data cannot give information about the exact recurrence rate. This implies that conclusions regarding the risk of reoperation are valid for recurrence only under the assumption that the studied variable (OT) cannot reasonably be supposed to influence the patients' decision whether to consent to reoperation. Admittedly, patients who consent to reoperation may, in many respects, differ from those who refuse, but this is not the question at issue. Instead, the question here is whether the studied variable could somehow affect the patients' willingness to consent to reoperation. For instance, we found a negative association between OT and RR for reoperation. To explain the appearance of this negative association in the absence of a similar association between OT and recurrence, we must assume the patients of surgeons with low OTs to be significantly more eager to submit to reoperation than those of surgeons with high OTs. This possibility seems remote. It might be theorized that low OT could be linked to reduced postoperative discomfort, which in turn might influence the patient's decision to request reoperation. However, in practice, such requests are based on far weightier considerations such as the presence or absence of pain and the size of the recurrence. Therefore, the findings can be accepted as valid for recurrence.

Results from an earlier register-based study³ showed that an increase in volume above a certain minimum leads to improved results, probably via increased expertise. The

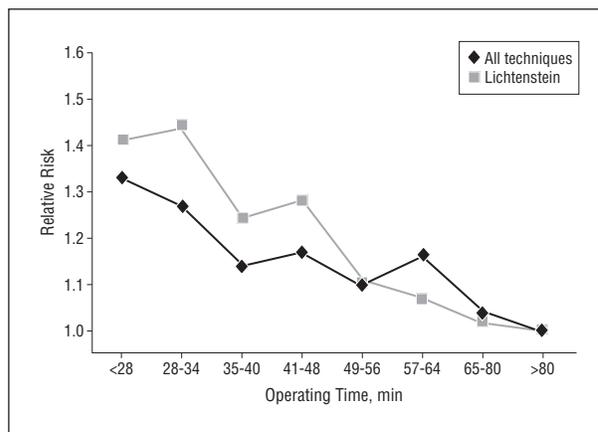


Figure 1. Relative risk for reoperation for recurrence in 8 operating-time groups, including all operative methods and selectively for the Lichtenstein procedure. The eighth group (>80 minutes) serves as the reference.

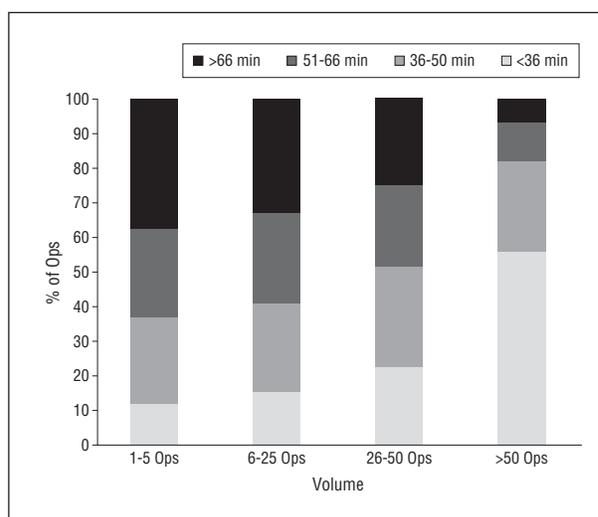


Figure 2. Relationship between surgeon's annual volume and operating time, including all operative techniques. Ops indicates operations.

present data suggest, however, that low OT may be a stronger risk factor for recurrence than low volume. The effect of low OT demonstrated its strength by not petering out rapidly at minor increases, as volume had done. The matter is further complicated by the strong negative correlation between OT and volume (Figure 2). High volume was firmly linked to low OT, which in turn was associated with a higher RR.

The variability of OT has, up to now, mainly been studied in efforts to come to grips with the variation's annoying and costly propensity to disrupt operating room schedules. Surprisingly, it was only fairly recently that Strum et al⁷ demonstrated that the single most important source of OT's variability is surgeon effect, and the implication of this variability for the results has not attracted much attention. The general impression seems to be that speed reflects skill, which in turn stems from experience gained by large volume, whereas prolonged operations are assumed to signify inexperience or trouble. The few studies on the subject seem to confirm at least part of this. Thus, the link between low OT and favorable results is apparent in a Norwegian study⁸ on total

Table 3. Relative Risk (RR) of Reoperation for Recurrence for Other Variables in the 4 Operating Time Groups^a

Variable	<36 min		36-50 min		51-66 min		>66 min		Total	
	RR (95% CI)	P Value								
Female sex ^b	1.35 (1.06-1.71)	.01	1.91 (1.47-2.47)	...	1.54 (1.11-2.15)	.01	1.37 (0.93-2.03)	.11	1.54 (1.33-1.78)	...
Age <60 y ^c	1.20 (1.04-1.37)	.01	1.09 (0.93-1.28)	.27	0.89 (0.75-1.07)	.23	1.07 (0.89-1.29)	.47	1.08 (0.99-1.17)	.07
Surgical volume, cases/year ^d										
1-5	1.59 (1.14-2.22)	.006	1.32 (0.97-1.80)	.07	1.88 (1.31-2.70)	.001	1.13 (0.77-1.66)	.54	1.46 (1.24-1.71)	...
6-25	1.21 (1.00-1.46)	.05	0.93 (0.75-1.15)	.51	1.52 (1.15-2.01)	.003	1.04 (0.76-1.43)	.81	1.17 (1.05-1.32)	.005
26-50	1.20 (0.99-1.46)	.07	0.91 (0.73-1.14)	.42	1.17 (0.86-1.58)	.32	0.76 (0.54-1.07)	.12	1.03 (0.91-1.16)	.64
Anatomy ^e										
Indirect	0.52 (0.45-0.60)	...	0.42 (0.36-0.50)	...	0.44 (0.36-0.54)	...	0.45 (0.37-0.55)	...	0.46 (0.43-0.51)	...
Femoral	0.47 (0.24-0.94)	.03	0.52 (0.27-1.01)	.05	0.82 (0.44-1.52)	.53	0.88 (0.50-1.54)	.65	0.66 (0.49-0.90)	.007
Combined	0.86 (0.63-1.18)	.35	0.58 (0.41-0.82)	.002	1.38 (1.06-1.81)	.02	0.65 (0.48-0.89)	.007	0.84 (0.72-0.97)	.02

^aMultivariate analysis according to Cox proportional hazards model.

^bVs male sex.

^cVs age ≥60 y.

^dVs >50 cases.

^eVs direct.

Table 4. Odds Ratios (ORs) for Complications and Selectively for Infection^a

Variable, by Operating Time, min	No.	OR (95% CI)
Complications		
<36	2482	0.72 (0.67-0.77)
36-50	2485	0.73 (0.69-0.78)
51-66	2323	0.86 (0.81-0.91)
>66	3178	1.00 [Reference]
Infection		
<36	322	0.54 (0.46-0.63)
36-50	394	0.66 (0.57-0.76)
51-66	347	0.69 (0.60-0.79)
>66	590	1.00 [Reference]

^aAdjusted for surgeon's annual volume, method of repair, emergency repair, age, sex, type of surgical clinic, and hernia anatomy.

hip replacement that found lengthy operations to be associated with a substantially increased revision rate due to aseptic and septic loosening of the implants. It also comes to the fore in the study by Pae and Carr,⁹ who found a connection between prolonged OT, high blood loss, and increased mortality after surgery for a ruptured abdominal aortic aneurysm. By contrast, in the present series, the presumed skill gained by volume manifested itself in speed but did not show up in outcome. Instead, low OT was linked to a higher reoperation rate.

So far, the effect of OT on the outcome of hernia surgery has not attracted much attention. Still, a recent prospective study from the Veterans Affairs Trials concerning inguinal hernia repair according to Lichtenstein found OT to be an independent predictor of recurrence. Operations lasting less than 72 minutes were associated with a significantly higher risk of recurrence than those lasting longer, and the average time difference between operations leading and not leading to recurrence was 9 minutes.^{10,11} Similar findings were reported by Sandblom et al,¹² who in a relatively small series found an increased risk for reoperation after very short operations. These results are in agreement with the present findings, and we have not

been able to locate studies postulating the opposite—that is, a positive correlation between OT and recurrence.

Whereas the RR for reoperation tended to decrease with higher OT, the incidence of infection and complications, such as hematoma and urinary retention, showed a marked increase with lengthening OT. In this respect, hernia surgery conforms to what is considered the rule in major surgery. However, the clinical significance of infection is limited. Deep infections are rare. When they occur, they do not have to lead to the removal of the mesh in cases where monofilament materials were used. Drainage and antibiotics are usually sufficient.¹³ Consequently, the strong association between lengthy OT and low-grade infection found here may have a more harmful effect on the outcome of major operations than it has in hernia surgery.

Thus, the study's findings can be summarized as follows. In its relation to infection, hernia surgery follows the general rule of other surgery: the longer the operation lasts, the greater is the risk of infection. As for technical failure (ie, recurrence), however, hernia surgery does not comply with the general rule because in other forms of surgery, such failure is linked to prolonged and not to short operations. How can this apparent paradox be explained? A possible explanation is that, in most forms of more complex surgery, threatening technical failure is often easily recognized during the operation. This recognition forces the surgeon to continue the surgery. In hernia surgery, however, the possibility of technical failure is not so easily recognizable. In hernia surgery, therefore, careful time-consuming repair may pay off. It is a sobering thought that W. S. Halsted's often quoted words, "Brilliance and speed must be subordinated to thoroughness and safety," are thus found to be valid for hernia surgery some 100 years later.¹⁴

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INVITED CRITIQUE

Too Much of a Good Thing or Operating at the Fringe

The relationship between surgical volume and performance continues to be a subject of considerable interest to surgeons, patients, and payors. In general, studies to date have made the intuitive observation that with increasing procedure frequency and/or surgeon experience, there is a proportional—and sometimes logarithmic—decline in operative time, operative time variability, and complication rate.¹⁻³ These findings are relevant in their implications for the allocation of finite operative resources, as well as for approaches to surgical education and continuing professional development.

In their examination of hernia repairs among patients in the Swedish National Register, van der Linden and colleagues⁴ both validate and expand on this base of understanding. Previous studies suggest that excessively long operative times (correlated with lower volume) are associated with higher rates of infection. Van der Linden et al now demonstrate a similar erosion in quality that may manifest at the opposite pole of efficiency; their findings imply that surgeons performing faster than a threshold operative time (correlated with higher volume) tend to demonstrate a higher rate of reoperation for hernia recurrence. Although this raises the possibility that frequency may sometimes breed complacency, we would argue that this study offers compelling evidence regarding the dynamic tension that exists between efficiency and safety at the extremes.

Although their analysis may be criticized for its failure to fully account for the gamut of patient- and provider-specific variables that may serve as covariates to their mea-

sured outcomes, such criticisms do not diminish the lessons offered by this investigation. By providing further insight into the dynamics at the fringes of efficiency and safety, van der Linden and colleagues⁴ advance our understanding regarding the limits to which performance improvement efforts can be taken and, therefore, enhance our notions of how such efforts can achieve maximal health care value.

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