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Point prevalence of surgical checklist use in Europe: relationship with hospital mortality

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Editor's key points

- Checklists promote recollection of recommended steps or actions, overcoming lapses in memory and attention.
- Clinical team participation in a checklist procedure should enhance communication.
- Checklists are a tool, not a replacement for adequate training and supervision, vigilance, and teamwork.
- The consistent relationship between checklist use and better outcomes probably indicates direct (causal) and indirect beneficial effects.

Background. The prevalence of use of the World Health Organization surgical checklist is unknown. The clinical effectiveness of this intervention in improving postoperative outcomes is debated.

Methods. We undertook a retrospective analysis of data describing surgical checklist use from a 7 day cohort study of surgical outcomes in 28 European nations (European Surgical Outcomes Study, EuSOS). The analysis included hospitals recruiting >10 patients and excluding outlier hospitals above the 95th centile for mortality. Multivariate logistic regression and three-level hierarchical generalized mixed models were constructed to explore the relationship between surgical checklist use and hospital mortality. Findings are presented as crude and adjusted odds ratios (ORs) with 95% confidence intervals (CIs).

Results. A total of 45 591 patients from 426 hospitals were included in the analysis. A surgical checklist was used in 67.5% patients, with marked variation across countries (0–99.6% of patients). Surgical checklist exposure was associated with lower crude hospital mortality (OR 0.84, CI 0.75–0.94; P=0.002). This effect remained after adjustment for baseline risk factors in a multivariate model (adjusted OR 0.81, CI 0.70–0.94; P<0.005) and strengthened after adjusting for variations within countries and hospitals in a three-level generalized mixed model (adjusted OR 0.71, CI 0.58–0.85; P<0.001).

Conclusions. The use of surgical checklists varies across European nations. Reported use of a checklist was associated with lower mortality. This observation may represent a protective effect of the surgical checklist itself, or alternatively, may be an indirect indicator of the quality of perioperative care.

Clinical trial registration. The European Surgical Outcomes Study is registered with ClinicalTrials.gov, number NCT01203605.

Keywords: checklist; hospital mortality; outcome assessment (health care)

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† See Supplementary file.

It is estimated that more than 230 million patients undergo surgery worldwide each year, with mortality rates reported to be between 1 and 4%.[1–3] Variations in mortality between hospitals suggest both the potential and the need to improve outcomes resulting from preventable adverse events.[3–9] Consequently, there is increasing focus on improving the quality of perioperative care to minimize adverse events, and hence postoperative mortality. The World Health Organization (WHO) surgical checklist is a simple intervention designed to reduce error rates during surgery and anaesthesia.[10] By improving communication within the surgical team, checklist use may improve hazard detection, leading to meaningful improvements in patient safety.[11 12]

The first report of the use of the WHO surgical checklist was a cohort study, in which implementation was associated with a decrease in adverse event rates from 11 to 7% and a reduction in mortality from 1.5 to 0.8%.[10] These preliminary findings were consistent with subsequent studies, with reports of reductions in adverse event rates[13 14] and mortality.[13–15] Checklists improve teamwork and communication in the operating theatre, which may be one explanation for improved patient outcomes.[16] These improvements in outcomes may also result in economic benefits.[17] Despite the strong arguments in support of surgical checklist implementation, there is anecdotal evidence of wide variation in use between hospitals and nations. However, there have been no international epidemiological studies of surgical checklist use, or associated mortality, to confirm or refute this proposition. The aim of our study was to describe the prevalence of surgical checklist use in patients recruited to the European Surgical Outcome Study (EuSOS),[3] and to establish whether there is any relationship between reported use of a surgical checklist and subsequent hospital mortality.

Methods

Data collection

This was a secondary analysis of the European Surgical Outcome Study (EuSOS) data set.[3] The EuSOS was an observational study including all patients aged 16 years and over undergoing non-cardiac surgery in participating hospitals during the 7 day cohort week between April 4 and April 11, 2011. Patients undergoing planned day-case surgery, cardiac surgery, neurosurgery, radiological, or obstetric procedures were excluded. A paper case record form was completed for consecutive eligible patients. This was then anonymized before data entry onto a secure Internet-based electronic case record form. Patients were followed up until hospital discharge for data describing hospital mortality, censored at 60 days after surgery. We assessed data for completeness and then checked for plausibility and consistency with prospectively defined ranges. As part of the prospective data set, investigators were asked to record whether a surgical checklist was used in the care of each individual patient. No other details were requested regarding how the checklist was used. Ethical requirements differed by country. In Denmark, centres were exempt from ethical approval because the study was deemed to be a clinical audit. In all other nations, formal ethical approval was obtained. Informed consent was obtained from patients where required by local research ethics committees. A list of participating hospitals and full details of the methodology of the study can be found in the original publication.[3] To improve data quality, the primary analysis was performed on a data set that excludes sites with ≤10 patients and sites above the 95th centile for mortality. A sensitivity analysis was conducted on the entire data set.

Statistical analysis

The mortality outcome was defined as death in hospital within 60 days of surgery. Patients were categorized according to baseline demographics, including age, gender, smoking status, ASA physical status score, urgency of surgery, grade of surgery, surgical procedure category, and co-morbid disease. A single-level binary logistic regression model was used to conduct univariate analysis of the effect of surgical checklist use on hospital mortality. We then constructed a multivariate logistic regression model to compare the use of surgical checklist across these categories. Factors were entered into the multivariate logistic regression model according to their association with mortality in the univariate logistic regression analysis ($P<0.05$). To adjust for likely variations within countries and hospitals, a hierarchical three-level generalized mixed model was developed, with patients as the first level, hospital as the second level, and countries as the third level. The model was constructed with and without the surgical checklist as a variable in order to compare the effect on hospital mortality. Categorical variables are presented as *n* (%) and continuous variables as mean (SD). Findings are presented as odds ratios (ORs) with 95% confidence intervals (CIs). Adjusted ORs are presented with crude ORs for comparison. All data analysis was conducted using SPSS version 21 for Windows (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.). Statistical significance was set at $P<0.05$.

Results

The EuSOS database consists of 46 539 patients from 498 hospitals. Of these, 45 591 patients from 426 sites were included in the primary analysis, with an overall hospital mortality of 3.0%. Baseline data are presented in Table 1 along with the likelihood of exposure to a surgical checklist according to these factors. There was wide variation in exposure to a surgical checklist according to baseline characteristics. The overall prevalence of surgical checklist use in this population was 67.5%, but there was marked variation between countries from 0 to 99.6%. There was no clear relationship between patterns of checklist use and mortality rates in individual countries (Fig. 1 and Supplementary Table 1).

The use of a surgical checklist was associated with a lower crude hospital mortality (OR 0.84, CI 0.75–0.94; $P=0.002$). This effect was strengthened after adjustment for baseline risk factors in a multivariate regression model (adjusted OR 0.81, CI 0.70–0.94; $P<0.005$). To account for the effect of variation within countries and hospitals, we then

Table 1 Baseline data describing differences in exposure to a surgical checklist. Odds ratios with 95% confidence intervals (CIs) were constructed for use of surgical checklist using multivariate logistic regression analysis, adjusting for age, ASA class, urgency of surgery, grade of surgery, surgical speciality, and the presence or absence of co-morbid disease. COPD, chronic obstructive pulmonary disease

Baseline data	Number of patients (%)	Checklist use (%)	Odds ratios (95% CI) for checklist exposure	*P*-value
Men	22 126 (48.5%)	67.3	0.96 (0.92–1.00)	0.06
Current smoker	9669 (21.2)	65.6	0.93 (0.88–0.97)	<0.001
ASA class				
I	11 400 (25.0)	68.2	Reference	–
II	21 122 (46.3)	67.5	0.85 (0.81–0.90)	<0.001
III	11 362 (24.9)	66.8	0.80 (0.74–0.86)	<0.001
IV	1527 (3.3)	65.0	0.67 (0.59–0.76)	<0.001
V	88 (0.2)	59.1	0.46 (0.30–0.76)	<0.001
Grade of surgery				
Minor	11 838 (26.0)	64.0	Reference	–
Intermediate	21 793 (47.8)	65.9	1.08 (1.03–1.13)	<0.001
Major	11 863 (26.0)	73.5	1.50 (1.41–1.59)	<0.001
Urgency of care				
Elective	34 284 (75.2)	66.6	Reference	–
Urgent	8778 (19.3)	70.2	1.16 (1.10–1.23)	<0.001
Emergency	2519 (5.5)	70.2	1.16 (1.05–1.27)	<0.001
Surgical procedure category				
Orthopaedics	11 877 (26.1)	71.6	1.42 (1.31–1.55)	<0.001
Breast	1482 (3.3)	74.1	1.72 (1.50–1.98)	<0.001
Gynaecology	3900 (8.6)	67.8	1.26 (1.14–1.40)	<0.001
Vascular	2334 (5.1)	63.9	1.09 (0.98–1.22)	0.13
Upper gastrointestinal	2183 (4.8)	71.4	1.42 (1.26–1.60)	<0.001
Lower gastrointestinal	4871 (10.7)	70.5	1.32 (1.20–1.45)	<0.001
Hepatobiliary	2177 (4.8)	58.8	0.86 (0.77–0.97)	0.01
Plastic or cutaneous	2391 (5.2)	64.8	1.17 (1.05–1.30)	0.01
Urology	4824 (10.6)	67.7	1.28 (1.17–1.41)	<0.001
Kidney	457 (1.0)	73.1	1.46 (1.17–1.82)	<0.001
Head and neck	5565 (12.2)	61.4	1.01 (0.93–1.11)	0.80
Other	3387 (7.4)	61.8	Reference	–
Co-morbid disease				
COPD	5075 (11.1)	72.3	1.37 (1.28–1.47)	<0.001
Coronary artery disease	6121 (13.4)	61.1	0.68 (0.64–0.73)	<0.001
Diabetes (not taking insulin)	3417 (7.5)	64.9	0.90 (0.83–0.97)	0.01
Hospital mortality (%)	1362 (3.0)	57.4	0.65 (0.59–0.71)	<0.001

constructed a three-level mixed model (Table 2). The findings of this analysis suggest that exposure to a surgical checklist is associated with lower hospital mortality (adjusted OR 0.71, CI 0.58–0.85; $P<0.001$). In a sensitivity analysis including all patients in the original EuSOS cohort (i.e. not excluding sites recruiting a small number of patients or those above the 95th centile for mortality), the equivalent three-level generalized mixed model was constructed, with similar findings (Supplementary Table 2). Exposure to a surgical checklist was associated with lower crude hospital mortality (OR 0.64, CI 0.59–0.71; $P<0.001$), although this effect was reduced after adjustment for confounding factors (adjusted OR 0.88, CI 0.77–1.01; $P<0.06$). Whilst mortality after surgery increases with more urgent surgical procedures, the apparent protective effect of the surgical checklist remains, regardless of the urgency of surgery (Supplementary Table 3).

Discussion

The principal finding of our study was that there were wide variations in exposure to surgical checklist use between European nations. Exposure was associated with a lower hospital mortality after adjustment for risk factors, which may differ between hospitals and countries. Overall, only two-thirds of patients who underwent surgery in this study were exposed to a surgical checklist. The findings of a sensitivity analysis including all hospitals were similar, although the observed effect of the checklist was weaker. It is unclear whether these observations relate to a protective effect of the surgical

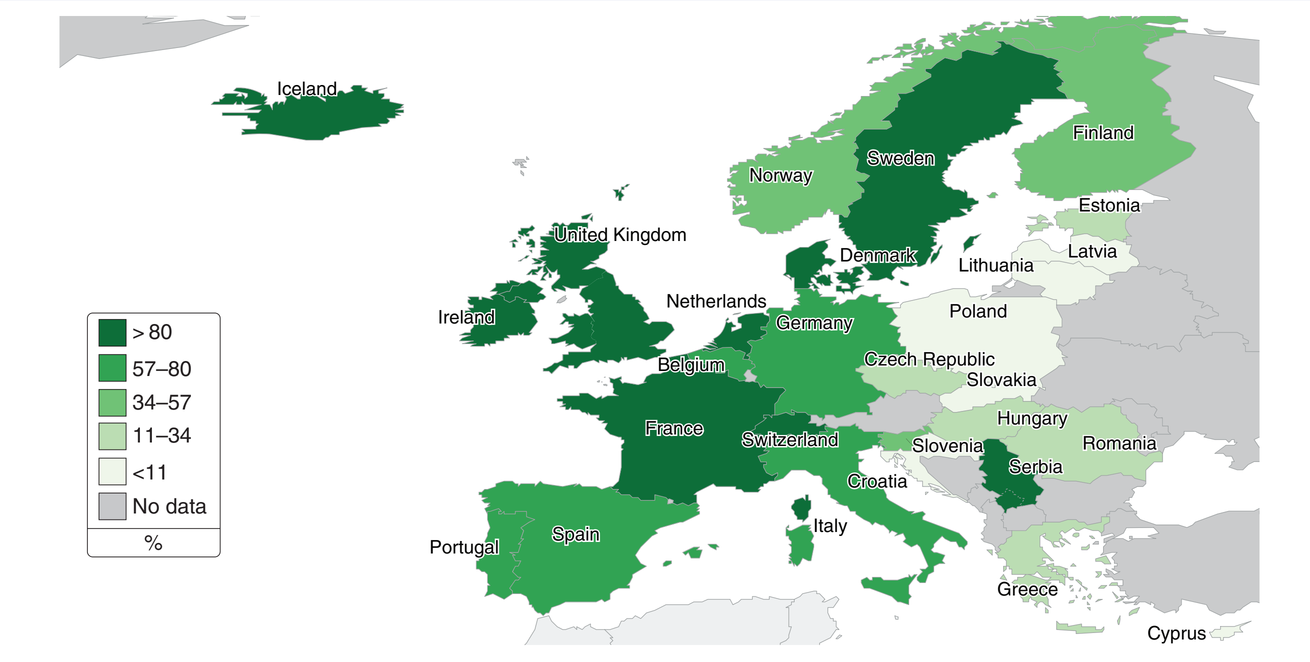

Fig 1 Proportion of patients exposed to a surgical checklist in different European countries.

checklist itself or whether this is merely a process measure reflecting higher quality of perioperative care.

The surgical checklist has been widely adopted in nations of differing economic status.[12] This hospital-level intervention cannot be studied in a simple randomized trial, and we must therefore depend on alternative methods of health services research to test the effects of exposure to a checklist, in particular, associations with mortality. The original report by Haynes and colleagues[11] described a simple cohort study of cluster trial design, suggesting that the checklist was associated with a reduction in postoperative mortality. Whilst these findings were the subject of debate, the outcome of two subsequent studies, a cluster trial and a retrospective epidemiological study, both from The Netherlands, also indicated an association with improved mortality.[14 15] A prospective study in orthopaedic patients did not show any association with reduced mortality, but suggested that early education and system change can increase accurate use and staff perception of the checklist.[18] There are, however, a number of reports that do not include mortality data, and it has been suggested that this may represent reporting bias.[12] Our study makes an important addition to the literature not only because it includes by far the largest number of patients, but also because this is the first study to allow comparison of checklist use and effectiveness in different health-care systems. This allows us to account for differences in national and local health-care policies. Our effect estimates are consistent with those reported in a previous systematic review (OR 0.57, CI 0.42–0.76), although the authors also describe significant heterogeneity of the literature, making interpretation difficult.[13] The findings of a further systematic review also suggested an association between checklist use and reduced mortality, and the authors noted that none of the component studies described any adverse effects on patient outcome.[19] The surgical checklist appears to be a low-cost, effective method that need not adversely affect operation room efficiency.[20] Other studies suggest a reduction in health-care costs associated with this intervention, presumably as a result of cost savings through reduced postoperative morbidity.[17 21] The introduction of a surgical checklist to the operating theatre environment appears to improve communication and teamwork within the multidisciplinary team, which in turn is associated with improvement in postoperative outcomes.[16 22] However, the assumption that introduction of a checklist improves communication in the absence of change in organizational structures has been questioned. Effective implementation of the surgical checklist requires strong clinical engagement with adequate staff training. A failure to do so may result in poor compliance or poor record keeping regarding checklist use.[23] In a recent study from Canada, the government-mandated implementation of a surgical checklist was not associated with a decrease in mortality.[24]

This prospectively collected data set provides a unique opportunity to evaluate the effect of the surgical checklist on hospital mortality. However, our analysis also has some limitations. The EuSOS was a 7 day cohort study of just under 500 hospitals in 28 European countries. The study design was necessarily pragmatic and not designed specifically to provide data on checklist use. We did not collect detailed data describing checklist implementation, such as the type of checklist used, duration of use, or the approach to implementation. Consequently, this analysis cannot confirm whether the observed

Table 2 Relationship between surgical checklist exposure and hospital mortality as in a three-level hierarchical generalized mixed model. *Unadjusted odds ratios (ORs) with 95% CIs were constructed for in-hospital mortality including the use of a surgical checklist and the relevant category in the model. †Mortality without the use of a surgical checklist. Odds ratios were adjusted for baseline risk factors of age, sex, country, ASA class, urgency of surgery, grade of surgery, surgical speciality, and the presence of metastatic disease or cirrhosis in a three-level binary generalized linear mixed model (with patient as first level, hospital as second level, and country as third level). ‡Odds ratios were adjusted for use of a surgical checklist and the baseline risk factors mentioned above. N/A, not available

	Unadjusted OR (95% CI)* for mortality	Adjusted OR (95% CI) for mortality excluding surgical checklist in model†	Adjusted OR (95% CI) for mortality including surgical checklist in model‡	*P*-value
Checklist use	0.84 (0.75–0.94)	N/A	0.71 (0.58–0.85)	<0.001
Age (yrs)	1.02 (1.02–1.03)	1.01 (1.01–1.02)	1.01 (1.01–1.02)	<0.001
ASA class				
I	Reference	Reference	Reference	–
II	0.99 (0.84–1.17)	0.77 (0.63–0.99)	0.76 (0.63–0.92)	0.01
III	2.14 (1.81–2.52)	1.29 (1.05–1.59)	1.29 (1.05–1.59)	0.02
IV	10.88 (9.00–13.17)	4.47 (3.50–5.72)	4.43 (3.46–5.66)	<0.001
V	56.80 (36.58–88.20)	15.49 (9.35–25.67)	15.40 (9.28–25.55)	<0.001
Grade of surgery				
Minor	Reference	Reference	Reference	–
Intermediate	0.93 (0.80–1.07)	0.81 (0.69–0.94)	0.81 (0.69–0.95)	0.01
Major	1.98 (1.72–2.29)	1.22 (1.04–1.44)	1.24 (1.05–1.46)	0.01
Urgency of care				
Elective	Reference	Reference	Reference	–
Urgent	0.93 (0.80–1.07)	1.85 (1.61–2.12)	1.84 (1.60–2.11)	<0.001
Emergency	1.98 (1.72–2.29)	3.08 (2.55–3.71)	3.02 (2.50–3.64)	<0.001
Surgical speciality				
Orthopaedics	0.80 (0.63–1.01)	0.79 (0.62–1.02)	0.76 (0.60–0.98)	0.04
Breast	0.77 (0.51–1.15)	1.04 (0.69–1.58)	1.05 (0.69–1.62)	0.79
Gynaecology	0.74 (0.55–0.99)	1.11 (0.81–1.52)	1.05 (0.76–1.44)	0.76
Vascular	1.87 (1.42–2.45)	1.09 (0.82–1.46)	0.94 (0.70–1.23)	0.69
Upper gastrointestinal	2.35 (1.80–3.06)	1.72 (1.30–2.29)	1.66 (1.23–2.22)	<0.001
Lower gastrointestinal	1.72 (1.35–2.18)	1.19 (0.92–1.55)	1.15 (0.88–1.50)	0.30
Hepatobiliary	1.24 (0.91–1.68)	1.10 (0.80–1.53)	1.09 (0.79–1.51)	0.60
Plastic or cutaneous	0.85 (0.61–1.19)	1.05 (0.75–1.48)	0.92 (0.65–1.30)	0.65
Urology	0.81 (0.62–1.07)	0.89 (0.67–1.19)	0.76 (0.56–1.02)	0.07
Kidney	0.46 (0.20–1.06)	0.37 (0.16–0.87)	0.33 (0.14–0.77)	0.01
Head and neck	0.78 (0.59–1.02)	1.17 (0.89–1.55)	1.04 (0.78–1.39)	0.79
Other	Reference	Reference	Reference	–

pattern of mortality is the direct result of the checklist itself or simply a feature of hospital processes which identify patient care of a higher quality. Data were collected during 1 week in April, which could mask the possibility of seasonal variation in outcome. The findings of the primary EuSOS study have been widely debated and subject to some criticism.[25–32] In some countries, the findings appear to differ from those from alternative data sources. In common with most registry data, it was not possible to undertake source data verification; hence, we cannot provide any measure of the quality of data collected. However, we also note that the findings of several retrospective analyses have suggested that our data have face validity, in particular after exclusion of hospitals returning very small numbers of patients.[33] One explanation for the high mortality in the parent study may be that investigators made a particular effort to include major or complex surgery, with the result that low-risk surgical procedures were under-represented. This would explain the high mortality on the one hand and the face validity of the data on the other. As in all epidemiological studies, the approach to hospital inclusion and patient sampling will influence the results. This could explain differences in the prevalence of checklist use between our work and other national studies.[34 35] It is also important to note that the simple prevalence of checklist use may not represent how carefully and effectively the checklist was used for individual patients.[36 37] Compliance with policies for checklist use may be lower than indicated by administrative data,[37 38] which may overestimate the true prevalence of checklist use in individual patients.[35] One factor that may influence compliance with checklist use is the urgency of surgery. It is interesting to note, therefore, a similar pattern of findings associated with checklist use in the EuSOS cohort regardless of the urgency of the surgical procedure.

Conclusions

The findings of this analysis suggest large variations in prevalence of surgical checklist use between European nations for patients undergoing inpatient non-cardiac surgery. Exposure to a surgical checklist was associated with reduced hospital mortality after adjustment for a range of other risk factors in a multilevel statistical model. This observation may represent a genuine protective effect of the surgical checklist itself, or alternatively, this intervention may be an indirect indicator of quality of patient care.

Supplementary material

Supplementary Material is available at *British Journal of Anaesthesia* online.

Authors' contributors

All collaborators were involved in data collection. I.J., T.A., and R.M.P. were responsible for the analysis design. T.A. provided statistical expertise. I.J., T.A., and R.M.P. drafted the manuscript, and all authors contributed to the interpretation of the results and critical revision of the manuscript for important intellectual content and approved the final version. I.J. and R.M.P. are the guarantors. All authors had access to the data and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Declaration of interest

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Data sharing

The authors are happy to consider data-sharing requests from bona fide researchers. These should be addressed to the senior author at: r.pearse@qmul.ac.uk.

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