

Effects of structured intraoperative briefings on patient outcomes: multicentre before-and-after study

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Abstract

Background: Operations require collaboration between surgeons, anaesthesia professionals, and nurses. The aim of this study was to determine whether intraoperative briefings influence patient outcomes.

Methods: In a before-and-after controlled trial (9 months baseline; 9 months intervention), intraoperative briefings were introduced in four general surgery centres between 2015 and 2018. During the operation, the responsible surgeon (most senior surgeon present) briefed the surgical team using the StOP? protocol about: progress of the operation (Status), next steps (Objectives), possible problems (Problems), and encouraged asking questions (?). Differences between baseline and intervention were analysed regarding surgical-site infections (primary outcome), mortality, unplanned reoperations, and duration of hospital stay (secondary outcomes), using inverse probability of treatment (IPT) weighting based on propensity scores.

Results: In total, 8256 patients underwent surgery in the study. Endpoint data were available for 7745 patients (93.8 per cent). IPT-weighted and adjusted intention-to-treat analyses showed no differences in surgical-site infections between baseline and intervention (9.8 versus 9.6 per cent respectively; adjusted difference (AD) -0.15 (95 per cent c.i. -1.45 to 1.14) per cent; odds ratio (OR) 0.92 , 95 per cent c.i. 0.83 to 1.15 ; $P = 0.797$), but there were reductions in mortality (1.6 versus 1.1 per cent; AD -0.54 (-1.04 to -0.03) per cent; OR 0.60 , 0.39 to 0.92 ; $P = 0.018$), unplanned reoperations (6.4 versus 4.8 per cent; AD -1.66 (-2.69 to -0.62) per cent; OR 0.72 , 0.59 to 0.89 ; $P = 0.002$), and fewer prolonged hospital stays (21.6 versus 19.8 per cent; AD -1.82 (-3.48 to -0.15) per cent; OR 0.87 , 0.77 to 0.98 ; $P = 0.024$).

Conclusion: Short intraoperative briefings improve patient outcomes and should be performed routinely.

Lay summary

Outcomes of surgery depend on patient characteristics and surgeon expertise, but also on teamwork, notably communication. The present study introduces the StOP? protocol, in which the surgeon informs the team about the current status (St), objectives regarding next steps (O), and potential problems (P), and encourages the team to ask questions and raise concerns (?). The results suggest an effect of the StOP? intervention on patient mortality, risk of unplanned reoperation, and duration of hospital stay, but not on surgical-site infections. The study is promising regarding the effect of structured intraoperative communication on important patient outcomes.

The study compared patient outcomes at baseline and after implementation of the StOP? protocol, which enhances exchange of structured information within the interdisciplinary surgical team during the course of the operation. The intention-to-treat analyses in this multicentre before-and-after study of 8256 patients undergoing general surgery showed no differences between baseline and intervention for surgical-site infections, but revealed reduced mortality and unplanned reoperations, and fewer prolonged hospital stays during the intervention period.

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Introduction

Worldwide, around 313 million surgical operations are performed annually¹ and 4.2 million patients are estimated to die within 30 days of surgery². Operations are performed in multidisciplinary teams where surgeons, anaesthetists, scrub technicians, circulators, and other personnel cooperate closely^{3–8}. Evidence from non-interventional studies has demonstrated that intraoperative cooperation, including communication as a central part, influences surgical quality and patient outcomes^{9–13}. Intraoperative communication¹⁴ about the progress of the operation allows the surgical team to form a common understanding of the procedure in general (shared mental model) as well as of acute developments (situation awareness)^{15,16}. Updates about developments 'that could have a bearing on subsequent phases of the operation' enable team members 'to anticipate future resource needs'¹⁷. Conversely, inadequate communication, which is not an uncommon problem^{11,18}, hampers a common understanding and can risk patient safety.

The quality of intraoperative information exchange depends considerably on the surgeon who is responsible for the operation. It is the responsible surgeon who normally decides on the course of the procedure and on changes to intraoperative strategy, and who plans and performs the main surgical tasks. The responsible surgeon therefore holds exclusive information that may be useful for the entire team¹⁹. However, several aspects threaten high-quality intraoperative information exchange¹⁸. Surgeons perform difficult psychomotor tasks that require their full attention^{20–22}; at the same time, they lead the team and have to provide the information needed for team members to carry out their tasks appropriately^{23,24}. Switching attention between psychomotor and communication tasks often induces additional mental load²⁵, and can interrupt the surgical flow. Therefore, intraoperative tools are required to aid information exchange between the responsible surgeon and the surgical team without interference to technical performance.

In this study, an intraoperative, non-interruptive, structured, and flexible tool was developed to ensure the exchange of task- and cooperation-relevant information, named the StOP? protocol. The hypothesis of this study was that introducing the StOP? protocol would improve patient outcomes, taking into account other risk factors related to the patient and the procedure. Outcomes investigated were surgical-site infections (SSIs), mortality, unplanned reoperations, and duration of hospital stay; SSI was the primary outcome.

Methods

Study design and participants

A multicentre before-and-after study was undertaken in four Swiss hospital departments (2 university hospitals, and two non-university referral centres). A 9-month baseline period without intervention was followed by an introductory period of 1 month, and then a 9-month intervention period during which the StOP? protocol was used during operations. During the introductory period, the StOP? protocol was explained and discussed in meetings with surgeons, nurses, and anaesthetists, and interviews were conducted with responsible surgeons to discuss when the protocol would be best employed in their specific types of surgery. In addition, trained observers attended operations, so that questions could be discussed; they also gave feedback to the surgeons. The study start date was staggered over time in the four hospitals to allow sufficient time for the team to prepare and introduce the

intervention in each centre (centre 1: 1 May 2015 to 30 November 2016; centres 2 and 3: 1 September 2015 to 31 March 2017; centre 4: 1 September 2016 to 31 March 2018).

The study population included all operations carried out in the participating departments by surgeons of these departments. All participating departments performed abdominal surgery; however, some departments covered a wider range of operations, and these were also included (Table 1). Exclusion criteria were: patient age below 18 years, existing SSI, previous surgery at the same surgical site within the past 30 days, outpatient procedures not requiring general anaesthesia, and proctological surgery. The responsible surgeon was always board-certified. The study was approved by the ethical committees (leading committee: #161/2014). In three centres, inclusion was based on patient general consent; in the fourth, the local ethical committee waived explicit patient consent, and allowed inclusion of patients who did not refuse the use of their data. The study was registered with ClinicalTrials.gov (NCT02428179).

Study procedure

The intervention entailed structured intraoperative briefings (in addition to the already established WHO checklist) during surgical procedures. To undertake the StOP? protocol, the responsible surgeon summoned all team members present in the operating room and informed them in a loud and clear voice about the current status of the operation (Status), about next steps and proximal objectives (Objectives), and about potential upcoming problems (Problems), and then encouraged team members to voice their observations or to ask questions (?) (Video S1).

Timing and initiation of StOP? protocol

The StOP? protocol was developed for use during the normal course of an operation. It is not confined to specific time points but uses natural break points²⁶ during the operation. Natural break points are moments of transition between two phases of an operation (such as after inspecting the situs or before an anastomosis). Between such phases, the surgeon has an opportunity to focus on the situation as a whole, including team status, and to conduct a StOP? without feeling interrupted by it. Thus, the StOP? protocol is not primarily intended for emergency situations; rather, it includes quite mundane situations in which the team might profit from the information. The transmission of information is followed by an explicit request to the team to speak up^{27,28}, thereby facilitating active team member participation.

The StOP? protocol was initiated by the responsible surgeon and performed at least once per operation. It was up to the responsible surgeon to decide on an appropriate time. As team members were familiar with the processes involved, discussion could build on existing knowledge and did not usually require lengthy explanation.

Development and introduction

The StOP? protocol was developed by the research team as a collaboration between surgeons and work and organizational psychologists; anaesthetists, scrub technicians and circulators were consulted. It was developed based on research into: the content of instructions needed to foster team situation awareness²⁹; the characteristics of the StOP? as a short step back from the operation^{30–32}; timing that avoids task disruptions^{22,33}; and the issue of speaking up²⁷. Before the study, the procedure was tested and adapted in several operations. Instruction for the StOP? protocol was provided by specifically qualified work and organizational psychologists and a surgeon. It included written information, presentations for all

Table 1 Patient and surgical characteristics for all operations and separately for baseline, intervention, and intervention with documented StOP? periods

	Total (n = 8256)	Baseline (n = 4055)	Intervention (n = 4201)	Intervention period with documented StOP? Protocol (n = 2504)
Age (years)*	57.18(17.46)	57.07(17.49)	57.28(17.42)	58.31(16.71)
Women	3619 (43.8)	1740 (42.9)	1879 (44.7)	1114 (44.5)
BMI category†				
Underweight	289 (3.6)	139 (3.5)	150 (3.7)	73 (3)
Normal	3479 (43.1)	1714 (43.1)	1765 (43)	1064 (43.1)
Overweight	2509 (31)	1232 (31)	1277 (31.1)	794 (32.2)
Obese	1804 (22.3)	894 (22.5)	910 (22.2)	536 (21.7)
ASA physical status grade†				
I	954 (11.7)	508 (12.7)	446 (10.8)	222 (9)
II	4044 (49.6)	2024 (50.5)	2020 (48.8)	1226 (49.6)
III	2724 (33.4)	1292 (32.2)	1432 (34.6)	895 (36.2)
IV	415 (5.1)	185 (4.6)	230 (5.6)	126 (5.1)
V	13 (0.2)	2 (0)	11 (0.3)	5 (0.2)
Main operation type				
Appendectomy	737 (8.9)	384 (9.5)	353 (8.4)	108 (4.3)
Cholecystectomy	1147 (13.9)	532 (13.1)	615 (14.6)	333 (13.3)
Colorectal surgery	1093 (13.2)	518 (12.8)	575 (13.7)	394 (15.7)
Hernia surgery	1447 (17.5)	714 (17.6)	733 (17.4)	443 (17.7)
Bariatric surgery	553 (6.7)	300 (7.4)	253 (6)	171 (6.8)
Upper gastrointestinal surgery	343 (4.2)	178 (4.4)	165 (3.9)	108 (4.3)
Hepatopancreatobiliary surgery	718 (8.7)	338 (8.3)	380 (9)	299 (11.9)
Small intestinal surgery	577 (7)	278 (6.9)	299 (7.1)	153 (6.1)
Thyroid, parathyroid surgery	276 (3.3)	127 (3.1)	149 (3.5)	111 (4.4)
Transplantation (liver, kidney)	108 (1.3)	46 (1.1)	62 (1.5)	30 (1.2)
Renal, adrenal surgery	114 (1.4)	55 (1.4)	59 (1.4)	39 (1.6)
Thoracic surgery	254 (3.1)	136 (3.4)	118 (2.8)	88 (3.5)
Vascular	240 (2.9)	115 (2.8)	125 (3)	71 (2.8)
Other	649 (7.9)	334 (8.2)	315 (7.5)	156 (6.2)
Contamination level†				
Clean	3059 (37.7)	1457 (36.6)	1602 (38.9)	925 (37.3)
Clean-contaminated	3541 (43.7)	1772 (44.5)	1769 (42.9)	1172 (47.2)
Contaminated	834 (10.3)	406 (10.2)	428 (10.4)	250 (10.1)
Infected	670 (8.3)	350 (8.8)	320 (7.8)	136 (5.5)
Duration of surgery†				
Duration of surgery (h)*	2.16(1.58)	2.18(1.61)	2.15(1.56)	2.34(1.62)
Duration longer than t-value	2274 (27.7)	1147 (28.4)	1127 (26.9)	717 (28.7)
NNIS score†				
0	3257 (40.9)	1643 (41.9)	1614 (39.9)	967 (39.4)
1	2962 (37.2)	1408 (35.9)	1554 (38.4)	962 (39.2)
2	1431 (18)	699 (17.8)	732 (18.1)	429 (17.5)
3	322 (4)	172 (4.4)	150 (3.7)	94 (3.8)
Surgical access: open or converted†	3957 (48.6)	1984 (49.5)	1973 (47.7)	1163 (46.8)
Elective surgery†	5561 (67.4)	2766 (68.2)	2795 (66.5)	1920 (76.7)

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). NNIS, National Nosocomial Infection Surveillance. † n's vary because of missing data.

professional groups working in the operating room (surgeons, anaesthesia professionals, scrub technicians, and circulators), instructional videos, posters at hand-wash stations, on doors and operating room walls, and direct intraoperative and postoperative instructional feedback for surgeons during the introductory phase. During the intervention period, scrub technicians and surgeons received monthly feedback about compliance. Contamination between the baseline and intervention periods was minimized because the intervention period was started on a specific day for all operations in each hospital; data from the introductory period were not included in the analyses presented here.

Outcomes

Based on a previous study indicating an influence of communication within the surgical team on SSI¹⁰, surgical SSI, as defined by the Centers for Disease Control and Prevention criteria³⁴, within

30 days after surgery was selected as the primary outcome. SSIs were assessed by trained study nurses following the Swissnos SSI surveillance system guide³⁵. This guide follows the US National Healthcare Safety Network (former National Nosocomial Infection Surveillance, NNIS) standards, and includes follow-up calls after 30 days³⁶. For procedures documented in the Enhanced Recovery After Surgery Interactive Audit System in one centre (ERAS; Encare, Stockholm, Sweden), SSI assessment was based on this validated data set³⁷.

Secondary outcomes were mortality and rate of unplanned reoperation for non-infectious conditions within 30 days of surgery, and prolonged duration of hospital stay. As mean duration of stay for specific types of operation differed between hospitals, prolonged length of stay was calculated as above (*versus* below or equal to) the 75th percentile for each surgical type, separately for each hospital.

Compliance assessment and co-variables

Compliance with the StOP? protocol was assessed by scrub technicians during the intervention period on a standard reporting form. They reported whether one, two or three or more StOP? protocols were performed during a given operation. It was left to the surgeons to decide how many StOP? protocols were appropriate for each operation; compliance was documented if at least one StOP? was reported, constituting the basis for per-protocol (PP) analyses.

For confidentiality reasons, specific data about team members, including the surgeons, were not collected. Patient and surgical data were collected by trained study nurses who specialized in collecting this kind of data and were not directly involved in the project. The data collected is included in [Table 1](#). The NNIS risk index score was calculated; this includes ASA grade above III, surgical wound classification grade exceeding class II, and duration of surgery above the t-value³⁸.

Statistical analysis

For the sample size calculation, the incidence of the primary outcome, SSI, after abdominal surgery was estimated to be 9.25 per cent, based on previous local data. The aim was to detect a reduction in the overall incidence rate from 9.25 to 7 per cent. A power analysis with an α of 0.05 (one-tailed) and a power of 0.80, assuming normal approximation to binomial distribution, yielded a required number of 1823 operations in each study period, thus 3650 patients overall. Based on the projected surgical volume of the participating departments, the duration of the baseline and intervention periods was set at 9 months, and the two 9-month intervals were used as boundaries for the inclusion. Patients with missing data were excluded from analyses.

Differences between the baseline and intervention periods were examined using the χ^2 or t test, depending on the type of data. Intention-to-treat (ITT) analyses (comparing baseline with all operations during the intervention period) as well as per protocol \square PP \square analyses (comparing baseline with operations with at least 1 documented StOP?) were performed. Analyses were based on stabilized inverse probability of treatment (IPT) weights using propensity scores^{39,40}. IPT weighting allows minimization of treatment selection bias by inducing a balance in co-variables between the baseline and intervention period. A weight, estimated based on co-variables that are known or suspected to influence the allocation of an operation to the baseline versus intervention period, was assigned to each operation; it expressed the likelihood that this operation was part of the intervention group. Because propensity scores close to 0 may make the weight estimator unstable, the IPT weight was stabilized by multiplying it by the overall probability of being part of the intervention period.

The propensity score was estimated based on multivariable logistic regression. The variables included were patient characteristics (sex, age, BMI), surgery type, surgical risk factors (NNIS score), surgical access (open/converted versus minimal access), and urgency of procedure (emergency versus elective). Matching was done using the nearest-neighbour method. A caliper distance of 0.2 (standard deviations of logit of estimated propensity score) was defined, and co-variable balance was assessed using the standardized absolute mean difference for each variable included. Effects were evaluated using multivariable logistic regression including the stabilized IPT weight; for the adjusted models, patient age, BMI, type of surgery, NNIS score, surgical access, urgency, and hospital were included, because all these factors have been related to postoperative complications in previous

studies^{34,41}. $P < 0.050$ (2-tailed) was considered statistically significant. Statistical analyses were conducted using SPSS[®] version 25 (IBM, Armonk, NY, USA).

Results

Altogether, 8759 eligible operations were recorded ([Fig. 1](#)). A total of 503 operations were excluded because of lack of appropriate patient consent or patient follow-up, and 511 operations because of missing data, leaving 3819 operations during the baseline period and 3926 during the intervention period. Reports from scrub technicians about whether or not StOP? was performed were available for 3104 of the 3926 operations (79.1 per cent). For 2403 (77.4 per cent) of these 3104 operations, performance of a StOP? protocol was reported; the compliance rate was 61.2 per cent for all 3926 operations during the intervention phase. This is a conservative estimate of compliance; the 20.9 per cent of 3926 operations for which there was no report were regarded as non-compliant.

[Table 1](#) summarizes the demographic and clinical characteristics overall, and separately for the baseline period, the whole intervention period, and for all operations with documented StOP? implementation within the intervention period; further details are available in [Table S1](#). Overall, the incidence of SSI was 9.8 per cent, the mortality rate was 1.5 per cent, the rate of unplanned reoperations was 5.8 per cent, and duration of stay was above the 75 per cent percentile within each surgical category after 21.3 per cent of procedures.

The co-variable balance after propensity matching was good for both ITT matching ($\chi^2(19) = 1.555$; $P = 0.999$) and PP matching ($\chi^2(19) = 4.522$, $P = 0.999$); there were no co-variables with an imbalance greater than 0.2, and none of the absolute standardized mean differences exceeded 0.1 after matching. The variance ratio for continuous variables ranged between 0.896 and 1.069, indicating good balance. Details of the unmatched and matched samples are shown in [Table S2](#) and [Fig. S1](#) for ITT analyses, and in [Table S3](#) and [Fig. S2](#) for PP analyses.

Results estimating outcomes were IPT weighted and adjusted for patient age, BMI, NNIS risk score, type of main surgery, surgical access, urgency of surgery, and hospital. Unadjusted, and adjusted and IPT-weighted results for ITT analyses are shown in [Table 2](#) and [Fig. 2a](#), and those for PP analyses in [Table 3](#) and [Fig. 2b](#). IPT-weighted, but not co-variable-adjusted results are shown in [Table S4](#).

Comparing patients who had surgery during the baseline and intervention periods, the adjusted ITT analyses showed no difference in SSI (odds ratio (OR) 0.98, 95 per cent c.i. 0.83 to 1.15; $P = 0.797$), but reduced risk of mortality (OR 0.60, 0.39 to 0.92; $P = 0.018$), unplanned reoperation (OR 0.72, 0.59 to 0.89; $P = 0.002$), and prolonged hospital stays (OR 0.87, 0.77 to 0.98; $P = 0.024$). Similar results were observed for adjusted PP analyses ([Table 3](#)). The duration of surgery was longer for operations with a documented StOP? than for baseline operations in the univariable analysis ([Table S1](#)). ANCOVA was used to test whether this difference remained after adjusting for the same variables as in the other analyses (age, BMI, NNIS risk score, type of main surgery, surgical access, urgency of surgery, hospital, and stabilized IPT weight). Adjusted results yielded an estimated marginal mean duration of 2.24 (95 per cent c.i. 2.20 to 2.27) h for baseline operations, and 2.26 (2.21 to 2.23) h for operations with a documented StOP? ($F(1) = 0.546$, $P = 0.460$).

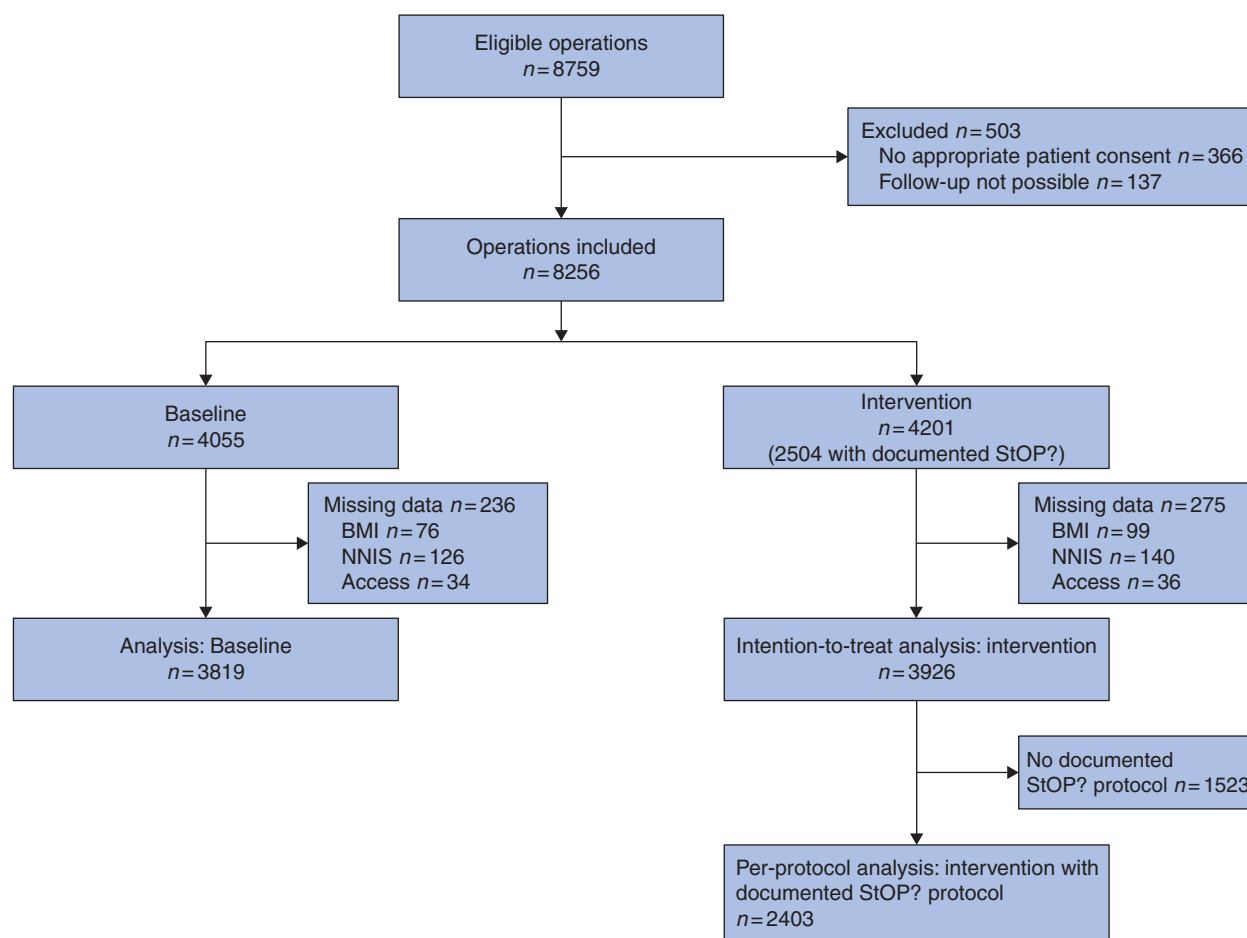


Fig. 1 Study flow diagram

NNIS, National Nosocomial Infections Surveillance; StOP? protocol, protocol in which the surgeon informs the team about the current status (St), objectives regarding next steps (O), and potential problems (P), and encourages the team to ask questions and raise concerns (?).

Table 2 Patient outcomes: descriptive statistics and outcome differences for intention-to-treat analyses (baseline versus intervention period)

	n	Unadjusted analysis			Adjusted analysis				
		No. of events*		P	Mean %†		Odds ratio‡	P	Mean difference (baseline - intervention) (%)‡
		Baseline	Intervention		Baseline	Intervention			
SSI**	7458	357 (9.8)	364 (9.6)	0.821	9.75(0.47)	9.59(0.46)	0.98 (0.83, 1.15)	0.797	-0.15 (-1.45, 1.14)
Mortality§	7745	60 (1.6)	42 (1.1)	0.053	1.59(0.18)	1.05(0.18)	0.60 (0.39, 0.92)	0.018	-0.54 (-1.04, -0.03)
Reoperation¶	5812	229 (6.5)	176 (4.8)	0.002	6.44(0.38)	4.79(0.37)	0.72 (0.59, 0.89)	0.002	-1.66 (-2.69, -0.62)
Prolonged stay#	7739	830 (21.8)	773 (19.7)	0.026	21.63(0.60)	19.82(0.59)	0.87 (0.77, 0.98)	0.024	-1.82 (-3.48, -0.15)

Values in parentheses are *percentages, †s.e.m., and ‡95 per cent confidence intervals. §Within 30 days after operation. ¶Reoperation for non-infectious complications; patients who died and those with surgical-site infection (SSI) were excluded from this analysis. #Duration of hospital stay above 75th percentile for a given surgical type and hospital; patients who died were excluded from this analysis. Analyses were adjusted for patient age, age, National Nosocomial Infections Surveillance score, BMI, type of main surgery, surgical access, urgency, hospital, and stabilized inverse probability weighting score. **Patients who died were excluded from this analysis.

Discussion

In this multicentre before-and-after study, the StOP? protocol had no effect on SSI rates but reduced mortality and unplanned reoperation rates, and prolonged hospital stays. By informing the operating team and focusing its attention on important aspects of the ongoing operation, the StOP? protocol may enhance a common understanding of the operation among team members by fostering a shared mental model and situation awareness^{15,29,42}. Common understanding promotes appropriate perception of

required actions and preparation for expected developments. The improved coordination that results allows for a smoother and more efficient flow of the procedure resulting in fewer interruptions and delays^{12,22,43}. By ending with a request for contributions from team members, the StOP? protocol encourages voicing of observations and speaking up, which reduces the risk of errors²⁷.

The StOP? protocol is anchored in research emphasizing the importance of teamwork, non-technical skills, and

communication for patient outcomes^{4,8,44}. Although largely observational, previous studies have indicated that teamwork quality, and notably communication, is associated with fewer surgical errors¹², and lower patient morbidity^{10,45} and mortality⁹ rates. The StOP? protocol complements checklists and team

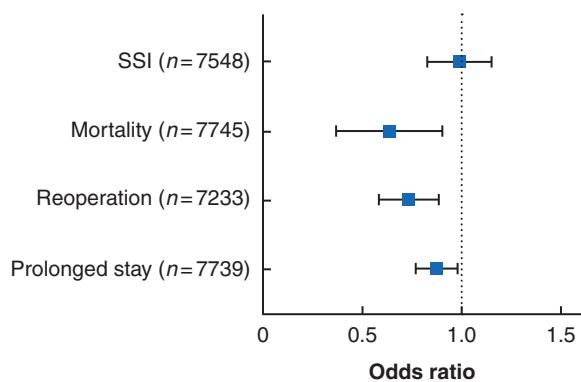
training as approaches to improve communication. Checklists such as the WHO Surgical Safety Checklist and the Surgical Patient Safety System focus on exchanging specific information, such as that relating to co-morbidities. Results of checklist implementation are promising with regard to surgical outcomes, including mortality⁴⁶⁻⁵³. However, there remains a lack of randomized studies, and previous research may be skewed by selection bias, given that the most consistent effects were found among hospitals that participated on a voluntary basis⁵⁴. WHO checklists are used at the beginning and end of an operation, whereas the StOP? protocol employs information exchange during the operation in a way that is specific enough to ensure that important information is exchanged; it is flexible enough to ensure that the information exchanged is relevant in light of ongoing developments, and it does not disrupt the surgery. In comparison with team training that focuses on teamwork and non-technical skills⁵⁵, the StOP? protocol does not require transfer from a training situation. Team training seems promising but has rarely been investigated in surgery^{56,57}.

It is not easy to explain the lack of effect of protocol implementation on SSI in the present study, as suggested by previous studies^{10,52}. Conceivably, SSI depends mostly on communication within the sterile team (assessed in a previous study)¹⁰, whereas the StOP? protocol influences communication among all team members including those outside of the sterile field (anaesthesia professionals and circulators)⁵⁸. In contrast to communication outside the sterile team, communication within the sterile team is more likely to refer to specific surgical actions and thus may be more pertinent to SSI.

This study was not an RCT, which limits conclusions in terms of causality. It cannot be generalized to all surgical procedures, and the results may differ for stable surgical teams. However, analyses based on stabilized IPT weighting reduce selection bias and make causal effects more plausible^{40,59}. Effects of unmeasured co-variables and of ongoing developments, such as refined surgical procedures, cannot be ruled out. However, no general changes in procedures were introduced in Switzerland during the study interval, and no hospital underwent reorganizations that might have improved patient outcomes.

Lack of compliance is among the main limitations for behavioural interventions, as observed with the WHO Surgical Safety Checklist^{52,60}. Despite careful introduction, regular feedback, and strong support from all department heads, documented compliance was only slightly higher than 60 per cent, similar to early implementations of the WHO checklist⁶¹. The compliance rate may have been underestimated in the present study, as StOP? protocols performed but not reported by the scrub technicians

a Intention-to-treat analysis



b Per-protocol analysis

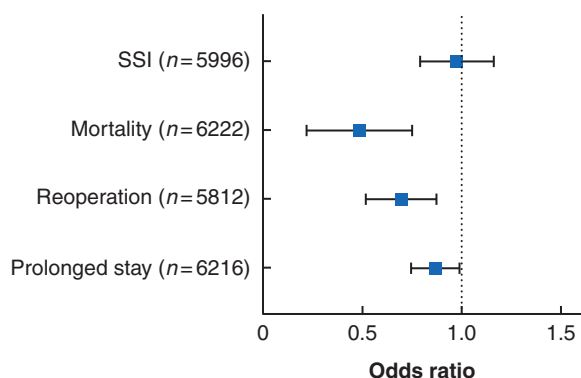


Fig. 2 Forest plots showing effects of intervention in intention-to-treat and per-protocol adjusted analyses.

Forest plots show odds ratios with 95 per cent confidence intervals for differences between baseline and intervention periods in surgical-site infections (SSIs), mortality, and reoperation for non-infectious complications within 30 days, and prolonged hospital stay (above the 75th percentile of duration of stay for each surgical type within each hospital) in **a** intention-to-treat and **b** per-protocol analyses. Analyses were adjusted for patient age, National Nosocomial Infections Surveillance score, BMI, type of main surgery, surgical access, urgency, hospital, and stabilized inverse probability weighting score. Patients who died were excluded from analysis of SSI, reoperation, and prolonged stay. Patients with SSI within 30 days were excluded from analyses of reoperation for non-infectious complications. Numbers on which each analysis are based are shown in parentheses.

Table 3 Patient outcomes: descriptive statistics and outcome differences for per-protocol analyses

	n	Unadjusted analysis			Adjusted analysis				
		No. of events*		P	Mean %†		Odds ratio‡	P	Mean difference (baseline – intervention) (%)‡
		Baseline	Intervention		Baseline	Intervention			
SSI**	5996	357 (9.8)	230 (9.9)	0.886	9.88(0.47)	9.64(0.6)	0.96 (0.80, 1.17)	0.701	-0.24 (-1.74, 1.30)
Mortality§	6222	60 (1.6)	17 (0.7)	0.003	1.54(0.18)	0.75(0.23)	0.44 (0.25, 0.77)	0.004	-0.79 (-1.36, -0.23)
Reoperation¶	5812	229 (6.5)	104 (4.6)	0.003	6.41(0.38)	4.67(0.48)	0.68 (0.53, 0.88)	0.003	-1.74 (-2.96, -0.53)
Prolonged stay#	6216	830 (21.8)	442 (18.4)	0.001	21.26(0.61)	19.2(0.77)	0.86 (0.75, 0.99)	0.042	-2.05 (-3.99, -0.12)

Values in parentheses are *percentages, †s.e.m. values, and ‡95 per cent confidence intervals. §Within 30 days after operation. ¶Reoperation for non-infectious complications; patients who died and those with surgical-site infection (SSI) were excluded from this analysis. #Duration of hospital stay above 75th percentile for a given surgical type and hospital; patients who died were excluded from this analysis. Analyses were adjusted for patient age, age, National Nosocomial Infections Surveillance score, BMI, type of main surgery, surgical access, urgency, hospital, and stabilized inverse probability weighting score. **Patients who died were excluded from this analysis.

were recorded as not occurring. Repeated training and evidence of effectiveness may increase compliance in the future, but high compliance may also require surgical teams to become acquainted with the StOP? protocol over an interval of more than 9 months. One may argue that some surgeons might do what the StOP? protocol aims to achieve anyway, whereas those not interested in such issues might not implement it. However, this argument cannot explain our results because possible effects of the StOP? protocol would actually be reduced if those who need it do not implement it, and those who implement it do not really need it.

Further research is required to investigate the mechanisms of the StOP? protocol regarding team processes in the operating room. The evidence presented here seems strong enough to justify investments in such research, and to encourage surgical departments to work with the StOP? protocol, gain experience, and evaluate its effects.

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Supplementary material

[Supplementary material](#) is available at BJS online.

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