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Does fluctuation in paramedical personal influence the morbidity of patients?

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Introduction

Colorectal surgery is associated with a high rate of postoperative complications compared to other surgical specialities, and reported morbidity rates reaching up to 35% (1)(2). Patients with complications after surgery are at increased risk of poor outcome and increased length of stay. Oncological patients are at particular risk as complications can delay the start of adjuvant therapy and thereafter influence negatively the rate of recurrence (1)(3). The most frequent complications related to colorectal surgery are surgical site infections, urinary tract infections and other surgical complications such as anastomotic leakage, ileus, bleeding and organ space infection (1)(4). The economic impact of complications after colorectal surgery is not trivial. A recent multicentre study showed that they can increase the costs per case from 26% for minor and up to 126% for major complications, respectively (5). An anastomotic insufficiency at its own can triple the costs (5). The risk factors for complications after colorectal surgery can be related either to the patients (older age, gender, specific comorbidities, ASA score) and/or to the surgical intervention such as prolonged operating time (>3 hours), surgical technique (laparotomy), intraoperative blood loss and lack of prophylactic antibiotics (5)(4).

Numerous strategies were developed to decrease the incidence of complications. Among them the Enhanced Recovery After Surgery (ERAS) protocols (in CHUV since 2011) have been implemented to optimize the peri-operative management. The rationale was to reduce the peri-operative stress response and organ dysfunction induced by surgical interventions (6). One of the major contributions of the ERAS program was to standardize the patient pathway before, during and after surgery. Important issues include standardized anaesthetic protocol, the use of minimal invasive surgery, postoperative management of pain, nutritional status, and early mobilization (7)(8). To provide the desired effect, this multidisciplinary approach requires a high compliance of the different health care professionals. It has been shown that an increase of 27% of the adherence to the ERAS protocol is associated to the same reduction of postoperative morbidity, postoperative symptoms and with a shorter length of stay (9)(10). More specifically in colorectal surgery, it decreases the postoperative complications by almost 50%. Our published data of the CHV series showed that ERAS has beneficial effects on the length of stay with a diminution of >2 days and on the direct cost per patient with a decrease of almost 2000 CHF (11).

Since the different guidelines of the ERAS society were published, several studies analysed how different items within these protocols could be optimized (12)(13). Interestingly, only few studies analysed the impact of paramedical staffing on postoperative outcome. Some authors suggested that an increase in the nurse-to-patient ratio decreases the postoperative complications whereas others could not show any correlations. For example, a low nurse-to-patient ratio was associated with a high rate of complications after oesophageal resection in one study (14)(15). To our knowledge, no studies analysed the effect of the nurse to patient ratio within the ERAS institutions.

The aim of this study was to analyse the relationship between the nurse workload and the occurrence of postoperative complications within an ERAS program for colorectal surgery.

Patients and methods

Study design, data base and protocol

This is a retrospective study based on a prospectively held database. The database includes data of all patients undergoing colorectal surgery at the Department of Visceral Surgery, Lausanne University Hospital. The CHUV is a recognized ERAS centre and as such collects prospectively a wide variety of data related to patient (preoperative phase, postoperative

phase and follow-up) enrolled in an ERAS pathway (16)(6). The information used in our study includes age, gender, BMI, diagnosis, surgical procedure, length of stay and the ASA score determined by the anaesthesiology team.

The study was approved by the Institutional Ethics Committee for Human Research (two protocols had to be submitted). While all consecutive patients were included in the clinical ERAS programme, only patients with a signed general consent could be used for research purposes.

Inclusion criteria

Between January 2014 to December 2016, 909 colorectal patients were included in the ERAS protocol. Patients operated in an emergency setting were also included. Laparoscopic and open surgeries were included as long as the patients were enrolled in the colorectal ERAS program.

Exclusion criteria

All patients younger <18 years or with other surgical procedures than colorectal surgery was excluded.

The amount of required daily nurse staffing is calculated on the estimation of the workload needed to treat an individual patient. Since 1992, this estimation is based in our institution on a program called *Projet de Recherche en Nursing (PRN)*. The PRN method is widely used in European countries, including Switzerland, France and Luxembourg. It assigns points to each patient according to the type of care needed (basic care, technical care, relational care), the category of care (hygiene, nutrition, comfort) and the specific care (intravenous medication, wound compression, rectal exam) (17). It predicts the time necessary for this individual patient care. The sum of all PRN on a specific ward provides an estimation of the number of nurses or equivalent full-time job (EPT) required to deliver this amount of care.

Each nurse reports daily the amount of care provided to each patient which provides the actual or real PRN values (18)(19). This nursing activity is collected prospectively in our institution in a database called the PRN system. The ratio between the total estimated PRNs and the actual PRN was used to assess whether the need for nurse staff has been adequately met.

The average real/required PRN rate between 2014 and 2016 was calculated. Based on this mean, we made two groups of patients: one having PRN values higher and a second having PRN values below this average. These two groups were used to compare the postoperative complications. For each group, the postoperative complication rate was calculated allowing us to make a comparison. The complications evaluated were: wound infections, urinary tract infection, surgical complications and infectious complications (defined as all infections other than urinary tract infections and wound infections, which include intraperitoneal abscess, sepsis and septic shock). Then, we compared the complication rate to the real/required PRN rate for each group of patients. This allowed to know if the complication rate varied with the real/required PRN ratio.

The complications were graded according to their severity using Clavien-Dindo classification (20). Minor complications are defined as grade I-II, whereas major complications as grade III-IV. Grade V complication is death. The therapy used to correct the complication is used to rank each complication (21). For each individual patient, more than one complication could be reported. Complications were shown as the number of patients with this specific complication.

The complication comprehensive index (CCI) was used to compile all complications per patient. The CCI is calculated as the sum of all complications that are weighted for their severity and is based on the Clavien-Dindo classification (22). The CCI value is used to rank the severity of complications from 0 (no complication) to 100 (death) in a single patient. CCI

integrates all events with their respective severity. The CCI was calculating for each patient with the CCI-calculator provided by the website [http://www.assessurgery.com\(23\)](http://www.assessurgery.com(23)).

The preoperative general status of patients (physical status) was measured according to the American Society of Anaesthesiologists (ASA). This score expresses the patient's preoperative health status and ranges from 1 (healthy patient) to 6 (brain dead state).

Statistics

Data were shown as mean with standard deviation, or percentages where appropriate. Standard statistical tests were used. Categorical variables were compared with Pearson's chi-square test. All statistical analysis was performed using MedCalc 18.11.

Results

1. Patient's characteristics

During the period studied, 909 patients were prospectively collected. There were finally 895 (98,5%) patients included, and 14 (1,5%) patients were excluded because they were younger than 18 years old. The patient's characteristics are detailed in Table 1.

Elective surgery was performed for 726 (81%) patients and emergency surgery was performed for 169 (19%).

While 276 (31%) procedures were performed open (laparotomy), the remaining 579 (65%) operations were performed laparoscopically. The conversion rate was 4,4% (40 operations).

The number of laparotomies did not vary between elective (n=221, 30%) and emergency surgeries (n=55, 33%). The majority of the operations were done laparoscopically (n=505 elective surgery; n=114 for emergency).

Number of patients included, <i>n</i>	895
Age, mean ± standard deviation (year)	63 ± 33
Male, <i>n</i> (%)	492 (55%)
Female, <i>n</i> (%)	403 (45%)
BMI, mean ± standard deviation (kg/m ²)	25.7 ± 4,6
Smoker, <i>n</i> (%)	266 (25%)
Immunosuppression, <i>n</i> (%)	94 (10%)
ASA 1, <i>n</i> (%)	42 (4%)
ASA 2, <i>n</i> (%)	575 (64%)
ASA 3, <i>n</i> (%)	263 (29%)
ASA 4, <i>n</i> (%)	15 (1%)
Length of stay, mean ± standard deviation (day)	12 ± 9

Table 1 patient's characteristics

2. Nurse staffing level

The average real/required PRN rate between 2014 and 2016 was 81.04%.

2. Operations and Complications

As illustrated in Table 2, the most common complications are surgical and infectious complications. On average, more complications occur after open surgery, wound complications being the most frequent. Urinary tract infections and surgical complications are more common following laparoscopic surgery.

Type of complications	Open surgery (n=276)	Laparoscopy (n=619)	Total
Overall Complication	152 (55,07 %)	296 (47,81%)	448
Infectious complication	72 (26,09%)	112 (18,09%)	184
Wound infection	70 (25,36%)	7 (1,13%)	77
Urinary tract infection	6 (2,17%)	40 (6,4%)	46
Surgical complication	62 (22,46%)	164 (26,5%)	226

Table 1 Complication rate for open surgery and laparoscopy

PRN and complications

To evaluate if the complication rates could be influenced by the staffing, we calculate the average real/required PRN rate between 2014 and 2016, as mentioned above. This rate was 81.04% and was used as a threshold to create two groups of patients. Then, we analyzed if the fluctuations of complications within both groups. 382 (42%) complications occurred with a PRN ratio <81.04% and 66 (8,1%) with a PRN ratio >81.04% (Table 3). No statistic differences were found between both groups (p -value = 0,71).

Complication at all during first stay			
PRN ratio overall group	No complication	Complications	Total
0= <81.04%	385	382	767 (85,7%)
1= >81.04%	62	66	128 (14,3%)
	447 (49,9%)	448 (50,1%)	895

Table 3. Overall complication rate for PRN group <81,04% versus PRN group >81,04%

We analyzed further the infectious complications. 158 (17,6%) complications occurred with a PRN ratio <81.04% and 26 (3%) with a PRN ratio >81.04% (Table 4).

Again, no statistical significant difference was observed (p -value = 0,94).

Infectious complications			
PRN ratio overall group	No complication	Complications	Total
0= <81.04%	609	158	767 (85,7%)
1= >81.04%	102	26	128 (14,3%)
	711 (79,4%)	184 (20,6%)	895

Table 4 Infectious complication rate for PRN group <81,04% versus PRN group >81,04

Wound infections occurred in 65 (7,2%) patients with a PRN ratio <81.04% (60 laparotomy and 5 laparoscopy) and 12 (1,4%) with a PRN ratio >81.04% (9 laparotomy and 3 laparoscopy) (p -value = 0,74) (Table 5).

Wound infection			
PRN ratio overall group	No complication	Complications	Total
0= <81.04%	702	65	767 (85,7%)
1= >81.04%	116	12	128 (14,3%)
	818 (91,4%)	77 (8,6%)	895

Table 5 Wound infections rate for PRN group <81,04% versus PRN group >81,04%

Urinary tract infection occurred in 42 (4,6%) patients with a PRN ratio <81.04% and 4 (0,5%) with a PRN ratio >81.04% (p -value = 0,26) (Table 6).

Urinary tract infection			
PRN ratio overall group	No complication	Complications	Total
0= <81.04%	725	42	767 (85,7%)
1= >81.04%	124	4	128 (14,3%)
	849 (94,9%)	46 (5,1%)	895

Table 6 Urinary tract infection rate for PRN group <81,04% versus PRN group >81,04%

All other surgical complications include anastomotic leak, urinary tract injury, mechanical bowel obstruction, post-operative paralytic ileus and intraoperative excessive hemorrhage. 192 (21,4%) complications occurred with a PRN ratio <81.04% and 34 (3,8%) with a PRN ratio >81.04% (Table 7).

There is no statistical significant difference between this two groups (*p-value* = 0,75).

Surgical complications			
PRN ratio overall group	No complication	Complications	Total
0= <81.04%	575	192	767 (85,6%)
1= >81.04%	95	34	129 (14,4%)
	670 (74,8%)	226 (25,2%)	896

Table 7 Surgical complications rate for PRN group <81,04% versus PRN group >81,04%

To determine if a lower PRN ratio could lead to an increase in the numbers of complications, we arbitrarily decrease the ratio to 60%. We obtained similar results with this ratio and no statistically significant differences could be found (Table 8).

PRN	Complications at all during primary stay	Wound infection	Urinary tract infection	Surgical complications	Infectious complications
<60	0.52	0.09	0.039	0.27	0.19
>60	0.55	0.08	0.053	0.24	0.20

Table 8 Post-operative complication rate for PRN group <60% versus PRN group >60%

Table 9 summarizes the relation between the PRN values and post-operative complication rate.

Summary of relationship between PRN and patient's outcome (Table 9)

	PRN < 81.04%	PRN>81.04%	p-value
Complications at all during first stay, n	382	66	0.71
Infectious complications, n	158	26	0.94
Wound infection, n	65	12	0.74
Urinary tract infection, n	42	4	0.26
Surgical complications, n	192	34	0.75

Table 9 This table summarize the relationship between PRN rate and patient's outcome

CCI

In our study, the mean CCI is 27,9, ranging from 18,7 to 76,4.

We also compared the CCI values for PRN rates < 81,04% versus >81,04%. No significant differences were found between the two compared groups (p -value=0,118).

To determine if a lower PRN ratio could lead to an increase of CCI values, the same comparison was performed by separating groups with PRN values < 70% versus PRN values > 70%. Finally, we compared the CCI values for PRN rate < 60% versus > 60%. Again, no statistical difference was found.

Discussion

To our knowledge, this is the first study analysing the relationship between the nurse workload and the occurrence of postoperative complications within an ERAS program. Our study suggests that the ratio between real /required PRN does not directly influence the occurrence of complications after colorectal surgery in an ERAS pathway.

909 colorectal patients were operated within our department during a period of 3 years and 895 were included in our study. This represents almost all colorectal patients operated at our institution as we do have the policy to include all patients within the ERAS protocol without restrictions. There were 169 out of 895 patients that were operated in an emergent setting. As recommended within the ERAS guidelines, laparoscopy was the preferred surgical approach in 65% of the time. Even in emergency situations, laparoscopy was preferentially used.

In our cohort, the overall rate of complication was 50.1%. The range of complications found in the literature is wide and is biased by the type of complications reported (24). Our complication rate encompasses all complication from minor grade I to major grade IV according to Clavien-Dindo classification. No death was reported during the period of study. In our study, the mean CCI is 27,9. The average CCI of our study corresponds to the values found in the literature (CCI values ranging from 20.9 to 37.2) (25)(26).

The rate of complications following colorectal surgery remains high even if the development of ERAS protocols was able to decrease it. Hence, there is an important need to further reduce postoperative morbidity and hospital costs. One possibility is to analyse the paramedical workload and staffing could impact on the occurrence of complications. We hypothesized that a lack of paramedical staffing could negatively influence the rate of complications. Thus, we used a program called *Projet de Recherche en Nursing* (PRN) to estimate the amount of nursing needed for a specific patient. As the allocation of resources never match the real needs, we used the ratio between the expected PRN and the actual PRN. On average, this ratio was 81.04%. We used this ratio as a threshold to create two groups of patients.

Our study shows that the complication rates did not differ statistically between both groups. Even by decreasing this ratio to 60% had no influence. These results were surprising but could be in part explained by the disadvantages of the PRN program. The PRN program was developed in 1969 without major modifications afterwards. Surgical interventions in the early 1970's had high morbidity rate, e.g. up to 50% of operations had infectious complications (27). Between 12-17% of operations are currently complicated by ileus, compared to 25% in 1966 (28). This is due to the fact that surgical techniques have improved, a multitude of new instruments for safer procedures have developed and patient preparation for surgery has evolved in recent years (29). Therefore, the resources allocation may probably be overestimated.

Nevertheless, these results are intriguing as they do not match with what is often

observed: nurses are more stressed and the percentages of absenteeism and burn-out is steadily increasing (30). One explanation is that the time gained on the care of patients must assigned to administrative work.

Studies showed that professional burnout syndrome affects 15-21% of nurses (up to 30% in a study of 2016) and 18% are at risk of burnout (30)(31). A French report shows an absenteeism rate of 8.1% for non-medical staff (32). Part of this stress can be explained by the increased complexity of the patients, the high expectancies on the outcome and the increased administrative load encountered. The surgical progresses relieved the need of direct bed-side cares but the intrinsic complexities of the patients and the system add new stressors that are not taken into account within the PRN system. Our study should allow new considerations to remodel the role of the paramedical personal on the surgical ward. The development of clinical nurses empowered with more medical responsibilities in some hospital is an interesting response to the increased complexity of health care. The system needs to be more reactive and the challenges is to combine the trend of hyper-specialization of surgery with the more general need of the patients. Rethinking the relationship between nurses and surgeons in a more intermingling way of working will not only diminish the unnecessary stress and burn-outs, but improve the patient safety in an ever-increasing complexity of health environment.

A more precise understanding of the potential link between postoperative complications and nurse workload could lead to an optimization of resources to decrease the adverse events and thereof the health costs.

Our results highlight two important points. First, the PRN system, which emerged from Canadian study in 1969 and used internationally, may not have adapted sufficiently to the evolution of surgery and patient management methods. Nowadays, the vast majority of patients underwent laparoscopic surgery, which was not the case in the 1970s. Major advances in laparoscopy occurred after the 1990s and gave birth to the fundamentals of modern laparoscopy. Since then, the evolution of the colorectal surgery is constant and thus very different from the 1970s, period of conception of the system PRN (33). Secondly, the emergence of the ERAS pathways may further explain these results as ERAS patients have a lower need for nursing care because of these protocols include elements other than nursing care. Indeed, most of the measures applied by the ERAS system do not depend on nursing work. The management of patients has been also modified as they are forced to their active participation in their own convalescence. The role of nurses is therefore modified, which explains why, despite the variation in nursing staffing, complications varies little. These results suggest that it is time to organize care teams in a different way and in particular to rethink the role of nurses in the overall care of patients. The role of nurses should be adapted to the emergence of ERAS and its consequences.

One proposition is that prehabilitation could be performed in patients at high risk for postoperative complications. It means that intervention measures should be taken before the operation on the patient's physical statue. A study showed that patients who deteriorated during prehabilitation had more complications and that the optimization of preoperative functional capacity could be beneficial (34).

Several limitations of this study need to be addressed. First, this study only concerns colorectal surgery. Further research should be conducted to determine if similar results are found for other types of surgery where laparotomies are more often performed. Moreover, our study is based on the PRN system to assess the care load. We might wonder what the results would be if we used another system to measure the workload of care used in other hospitals. Another point to mention is that the complication rate has not been adjusted to the risk factors of developing a complication for patients. This means that a linear regression should have

been used to assess the association between the PRN rate and the occurrence of post-operative complications.

Nevertheless, our study is the first to address the potential link between nurse staffing and complications. Our results suggest that we need to readdress manpower and nursing competencies in a more reasonable manner by increasing the responsibilities of the paramedical personal.

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