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ORIGINAL ARTICLE

Morbidity and mortality conference as part of PDCA cycle to decrease anastomotic failure in colorectal surgery

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Abstract
Background and aims Morbidity and Mortality meetings are an accepted tool for quality management in many hospitals. However, it is not proven whether these meetings increase quality. It was the aim of this study to investigate whether Morbidity and Mortality meetings as part of a PDCA cycle (Plan, Do, Check, Act) can improve the rate of anastomotic failure in colorectal surgery.
Materials and methods From January 1, 2004, to December 31, 2009, data for all anastomotic failures in patients operated on for colorectal diseases in the Department of Surgery (Klinikum Friedrichshafen, Germany) were prospectively collected. The events were discussed in Morbidity and Mortality meetings. On the basis of these discussions, a strategy to prevent anastomotic leaks and a new target were defined (i.e. 'Plan'). This strategy was implemented in the following period (i.e. 'Do') and results were prospectively analysed. A new strategy was established when the results differed from the target, and a new standard was defined when the target was achieved (i.e. 'Check, Act').
Results The year 2004 was set as the base year. In 2005 and 2006, new strategies were established. Comparing this period with the period of strategy conversion (2007–2009), we found a significant decrease in the anastomotic failure rate in colorectal surgery patients (5.7% vs 2.8%; $p=0.05$), whereas the risk factors for anastomotic failure were unchanged or unfavourable.
Conclusions If Morbidity and Mortality meetings are integrated in a PDCA cycle, they can decrease anastomotic failure rates and improve quality of care in colorectal surgery. Therefore, the management tool 'PDCA cycle' should be considered also for medical issues.

Keywords Morbidity and Mortality conference · PDCA cycle · Quality management · Colorectal surgery · Anastomotic failure

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Introduction

In many hospitals, Morbidity and Mortality (M&M) meetings are an accepted tool for quality management. In the literature, the educational aspect of M&M meetings has been emphasised [1]; however, the extent of the educational value has yet not been analysed.

It is also unclear whether or not quality management tools improve medical outcomes in practice. Systematic quality assurance is a method to measure the effects of specific quality factors. In German hospitals, those factors are commonly assessed using clinical studies, and they are typically analysed by a specific medical college or by an external committee.

These measured quality factors are also considered in the M&M meetings. However, this form of quality assurance seems to be incomplete in comparison to a complete recording of complications during an M&M meeting, as only a small subset of cases are recorded and discussed [2, 3].

For example, carrying out a survey of anastomotic leaks in colorectal surgery is the basis for quality improvement, but is it satisfactory? Generally speaking, M&M meetings

are useful for improving quality because the data are not only collected but are also discussed.

However, from a logical point of view, a condition for improvement is that additional strategy development (i.e. a change in the course of action) will take place, which should include setting goals and establishing control of the implementation.

To manage the transfer of measures, the so-called PDCA cycle has been developed [4]. In principle, this cycle can be applied to the field of medicine. The hypothesis can be advanced to the extent that the establishment of the PDCA cycle is a pre-existing condition for quality improvement.

The 'Plan' step involves assessing the collected data in comparison with a benchmark from other institutions or from own objectives, for example. In this section, a review of the literature and a discussion of M&M meetings are also considered.

In the 'Do' step, the new measures are transferred and continuously recorded.

In the 'Check' step, it is assessed whether or not the strategy has been changed and the targets have been met.

In the 'Act' step, successful strategies are established as the standard, and unsuccessful strategies are abandoned and replaced by new strategies.

In this study, we investigated if the continual recording of anastomotic leaks after colorectal resection and the development of new strategies to avoid anastomotic leaks in M&M meetings using the PDCA cycle format can decrease the frequency of anastomotic leak after colorectal resection.

Materials and methods

From January 1, 2004, to December 31, 2009, all undesirable events, including anastomotic leak, occurring in patients operated on in the Department of Surgery (Klinikum Friedrichshafen, Germany) were prospectively collected. Standardised documentation for every patient was used. A questionnaire recorded patient data, diagnosis, operative procedure and technique, and postoperative course. In addition, a critical analysis of diagnostic methods, indication for surgery, surgical techniques, operative course and risk factors for leakage were reported. By recording these data electronically, a statistical analysis could be performed.

Colonic anastomoses were performed with hand-sewn sutures. After a sigmoid or rectal resection, all anastomoses were stapled and checked intraoperatively with air insufflation.

Undesirable events, including anastomotic failures, were discussed in M&M meetings, and possible reasons for the complications were analysed. This information was then integrated into a PDCA cycle.

The principle of the PDCA cycle is shown in Fig. 1:

> Plan: During daily ward rounds, undesirable events are reported. In monthly M&M meetings, selected cases are discussed. A year's worth of data are presented annually. In these annual meetings, new strategies to prevent undesirable events (e.g. anastomotic leak), as well as new goals and benchmarks, are identified.

The target criteria of 'anastomotic leak' was defined using the definition in the literature [5], which is based on radiologic proof of an anastomotic leak or the production of air, pus or stool through a correctly placed drain.

Based on the data from 2004 and the benchmarks described in the literature, the objective for the following year was agreed upon. Analysis of the undesirable events during the M&M meeting was taken into consideration when developing the new strategy.

The basis for recording the initial data was data from 2004. After 2004, comparisons were made to the previous year and to the most recent internal benchmark.

> Do: The collection of data was performed as described above. The implementation of a new strategy was assessed during M&M meetings and during daily ward rounds. It was also assessed by checking the operation rates.
> Check: Data for 1 year was analysed. Based on this and the analysis during the M&M meeting, a new strategy was established.
> Act: In the following year, the new strategy was implemented. Recording and controlling the strategy was performed as described in the 'Do' step.

Statistical analysis was performed using SPSS software (version 15.0). The chi-square test or Fisher's exact test was used to assess differences in the distribution of patient characteristics and risk factors and the frequency of anastomotic leakage.

Results

During the time of observation, 706 colorectal resections took place (colonic resection $n=553$, rectal resection $n=153$). The overall mortality was 47/706 (6.5%; pneumonia $n=7$, intestinal ischemia $n=1$, sepsis $n=15$, lung embolism $n=5$, hemorrhage $n=1$, cardiac failure $n=5$, MOV $n=11$, renal failure $n=2$) and the overall morbidity is shown in Table 1. Hartmann procedures, trans-anal tumour resections and rectal extirpations were not taken into consideration for our study because the target 'anastomotic leak' does not play a role in these procedures. The remaining 637 colorectal resections (ileocolic resections, $n=45$; right colectomies, $n=142$; transverse colectomies, $n=48$; left

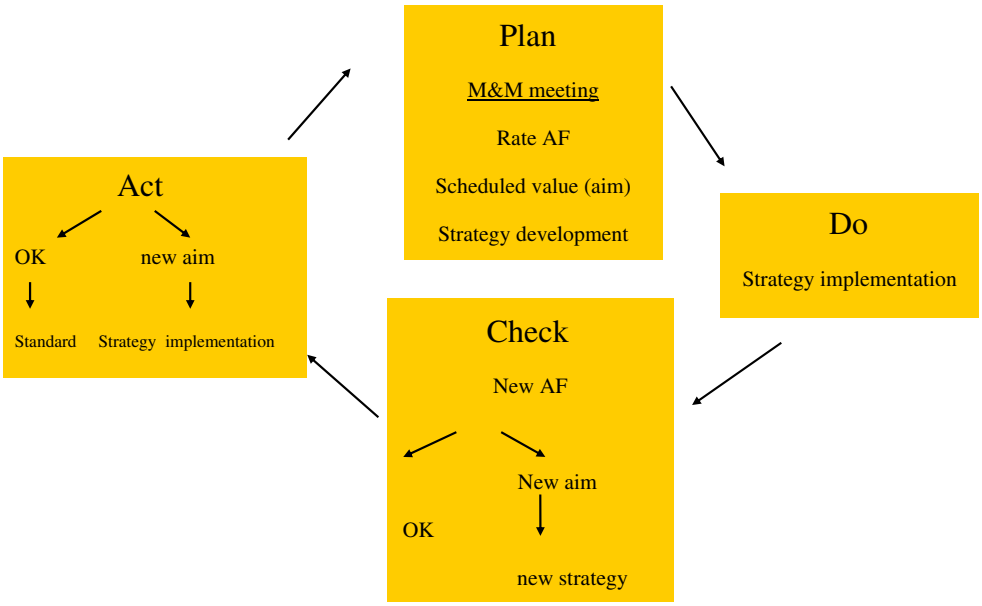

Fig. 1 PDCA cycle. *AF* anastomotic failure

colectomies, $n=44$; sigmoid colectomies, $n=262$; rectal resections, $n=96$) were analysed.

The year 2004 was used as the base year for evaluation.

During 2004, anastomotic leaks occurred in 5/102 (4.9%) resections. During the M&M meeting and the overall review of the year, it came to the department's attention that in 2004 there were 18 variations in the type of anastomotic sutures that were used. Besides the end-to-end stapled anastomosis and the side-to-side stapled anastomosis, there was an end-to-end, side-to-side and end-to-side hand-sewn sutures, using single or double rows of continuous or interrupted sutures.

Table 1 Overall morbidity in 637 patients with colorectal resections

Morbidity	Number
Wound infection	30
Anastomotic leakage	27
Pneumonia	10
Lung embolism	9
Burst abdomen	7
Cardiac failure	7
Ileus	5
Bladder dysfunction	5
Gastrointestinal bleeding	4
Aspiration	4
Abscess (intra-abdominal)	4
Ureteric injury	4
Small bowel injury	3
Port infection	1
Bowel ischemia	1
HIT	1

In three out of four resections that resulted in leaks, a single-layered, continuous, transmural, seromuscular anastomotic suture was used. Consequently, it was agreed upon that the continuous, single-layered technique should be abandoned as a strategy for preventing leaks in the upcoming year. The standard of care for anastomoses is suturing the back wall using a double-layered technique (first row continuous, second row interrupted) and single-layered, transmural, interrupted sutures in the front. In the region of the rectosigmoid area, the end-to-end stapled anastomosis remains the standard technique.

Controlling the theatre notes improved the strategy implementation rate from 98.4% to 100% in the years from 2005 to 2009. Further strategy development was based on the analysis of the anastomosis insufficiency**.** In 2005, the insufficiency rate was 9/115 (7.8%). Comparing these data with the results of the multi-centre study conducted by Marusch et al. (insufficiency rates of 3.7% after colonic resections and 9.5% after rectum resection [5]), there was a higher incidence of leaks in our patients. However in 2005, there was a 98.4% implementation rate of the new strategy (i.e. avoiding the single-layered continuous suturing technique). Due to this finding, it was agreed that in the next year (2006), an anastomosis would be performed only when there was pulsatile bleeding seen at the margin of the intestine, and the blood supply would have to be checked by diaphanoscopy. Documentation had to be written up in the theatre notes. Furthermore, since 2007 only two surgeons were allowed to perform rectal resections. In 2007, 2008 and 2009, the anastomotic leak rate after colonic surgery was continually reduced from 4/87 (4.6%) to 1/100 (1.0%) and in 2009 to 2/87 (2.3%). In rectal surgery, the leak rate changed from 1/17 (5.9%) to 1/13 (7.7%) to 0/16 in 2009. These changes were accompanied

by regular departmental teaching and controlling of the anastomotic strategies. Finally, a period of strategy development (period 1=2004–2006) could be discriminated from a period of strategy permutation (period 2=2007–2009). Comparing these two periods, we found a significantly decreased anastomotic leak rate in the second period (Fig. 2).

Comparing the risk factors, however, we found some significant disadvantages for period 2 (e.g. longer operative time, more smokers, more patients with alcohol abuse or atherosclerotic disease and more patients with immunosuppression; Table 2).

Discussion

It is unknown whether or not quality assurance efforts lead to improved quality. It seems unlikely as long as the assurance is only a measurement. For quality improvement, this measurement is an absolute necessity, but it is only one of the requirements that are needed.

For proper quality improvement, it is also necessary to establish a strategy that could have a positive effect on the outcome. Whether or not this strategy improves quality needs to be measured. This measurement process is called the PDCA cycle.

To our knowledge, this study describes the results of routine use of PDCA cycle in surgery for the first time. It was not the aim of the study to find new pathogenetic factors of anastomotic failure but to investigate whether the use of PDCA cycle can increase quality by decreasing the frequency of anastomotic failure. If so, the management tool 'PDCA cycle' should be considered also in this medical issue.

From 2004 until 2009, all unfavourable postoperative events after colorectal surgery were prospectively recorded.

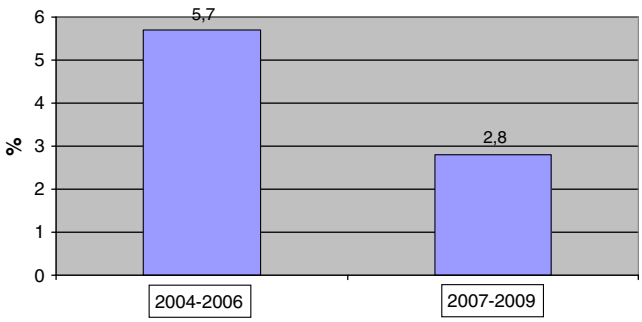

Fig. 2 Frequency of anastomotic failure before (2004–2006; n=18/317) and after (2007–2009; n=9/320) strategy implementation. There was a significant decrease in the leak rate in the second period (2004–2006 vs 2007–2009; p=0.05). Strategy 1: standardisation of suturing technique: the back wall with a double-layered technique (1st row continuous, 2nd row interrupted) and single-layered, transmural interrupted sutures in the front (2005). Strategy 2: standardisation of blood supply evaluation (2006). Strategy 3: two experienced surgeons for rectal resection (2006)

The PDCA cycle was established based on these data, and we established controlled strategies for quality improvement with regard to anastomotic leaks in M&M meetings.

We changed strategies in period 1 (2004–2006). In comparison to period 2 (2007–2009), there was a significant reduction in the anastomotic leak rate, but the risk factors were similar or worse.

In conducting the PDCA cycle, there are different points at which random errors can take place. In the 'Plan' step, the relevant data are recorded and the strategies are established. In the 'Do' step, implementation of the agreed strategies may not be properly executed.

Data collection

With regard to data collection, it is interesting to know that 58% of German hospitals record data on the postoperative course of their patients [6]. In 79 of these hospitals, patient records are used for the data collection. It is not known if an electronic information processing system could improve the quality of care. In this survey, 1,159 German hospitals were analysing their data with a response rate of 55%, and 79% of the hospitals were analysing their data on a leading consultant level only [6]. In just 45% of the hospitals, regular M&M meetings take place, and only 30% of them discuss their complications. In addition, the complete data collection of all unfavourable events seems impossible during the typical M&M meeting. In a survey comparing the data collected by the NSQIP (National Surgical Quality Improvement Program of the American College of Surgeons), it was demonstrated that only 25% of the relevant events had been collected in M&M meetings [2]. In the NSQIP, data collection is performed by a specialised nurse who looks through the patient records. In contrast, data from M&M meetings are usually collected by doctors who are not specially trained for such a task.

We have recorded all adverse postoperative events. To ensure the completeness of the data, we used the daily ward notes, the discharge letter and the theatre notes. A standardised questionnaire had to be used. This questionnaire recorded patient data, diagnosis, operative procedure, operative time and postoperative course. In addition, critical judgment regarding diagnostic indications, operative procedures and operative course were recorded. By using computerised data, annual analyses and comparisons were easily performed. The method of data collection was not changed over time.

Strategy development

The use of M&M meetings for strategy development and their influence on surgical quality has not been previously discussed. Currently, M&M meetings are used as a tool for

Table 2 Risk factors for anastomotic failure during the time period before (2004–2006) and after (2007–2009) strategy permutation

		2004–2006 (n=317)	2007–2009 (n=320)	2004–2006 vs 2007–2009
Anastomotic failure		18	9	p=0.05
Age (years)	≤50	33	30	p=0.117
	50–70	149	128	
	>70	135	162	
Sex	M	162	168	p=0.392
	F	155	152	
ASA	1 or 2	152	143	p=0.272
	3 or 4	165	177	
OP time (min)	≤120	23	30	p=0.024
	120–240	205	434	
	>240	89	150	
Contamination rate	B	232	232	p=0.238
	K	28	40	
	S	57	48	
PVD		29	30	p=0.52
Ileus		37	41	p=0.375
Emergency		66	72	p=0.338
CAD		88	72	p=0.075
Smoker		36	55	p=0.023
Alcohol abuse		24	39	p=0.034
Immunosuppression (steroids and/or chemotherapy and/or radiochemotherapy)		12	29	p=0.005
Diabetes mellitus		53	52	p=0.479
BMI	>25	172	176	p=0.49
	>30	63	43	p=0.017
OP technique	Open (o)	212	197	p=0.299
	Laparoscopic (l)	90	101	
	Conversion (l–o)	15	22	
Anus praeter		73	61	p=0.129
Rectal anastomosis (cm from anal verge)	0–4	19	22	p=0.617
	4–8	21	16	
	8–12	9	8	
	12–16	1	0	

identifying mistakes and initiating departmental discussions [7]. It remains unclear what is meant by the term 'discussion' and where the next occurs after the M&M meetings. M&M meetings are also used for educational purposes [8]. It is unclear if the PDCA cycle, which is used in other fields of management, has a beneficial effect on quality improvement in medicine. It seems unclear whether or not a simple discussion of a patient's medical course has a beneficial effect on future clinical practices. It is absolutely necessary to establish strategies to avoid negative events in the future after investigating of patient records and discussing the reasons for the adverse events. We have shown that incorporating the M&M meeting into the PDCA cycle can have beneficial effects on the parameter of interest (in this case, the anastomosis leak rate after colorectal surgery). For strategy development, we integrated our results with the results of the benchmark. In order to identify the external benchmark and our own internal benchmark (i.e. the last year), a clear definition of the parameter of interest is necessary. Only then can a comparison with internal and external data be made. We have used a definition based on realistic situations in a general hospital setting [5]. This definition could prospectively be used from 2004 on. In 2010, a grading system for anastomotic leaks of the rectum was published [9]. Using this grading system, all but two of our leaks were grade C leaks; the remaining two were grade B.

For strategy development, open analysis and discussion of the reasons for adverse events and how to avoid them is necessary during an M&M meeting. A condemnatory intention of the conference leads to defensive behaviour of the participants and is counter-productive [10, 11].

Studies have shown that 27% of the participants in M&M meetings describe an inadequate atmosphere in the conference, and 20% feel they are being condemned [10]. This atmosphere creates an obstacle for developing new strategies. We are trying to avoid such an atmosphere by having the case described by the surgeon and by including the relevant possible causes as a routine part of the description. We have used our personal judgement of the discussed case and an investigation of the literature for possible risk factors. With regard to anastomotic leak rates, the literature has identified weight loss >5 kg, hypoalbuminemia, coronary artery disease, ASA ≥3, history of blood transfusion, alcohol abuse, lack of bowel preparation, male gender, smoking history and septic operations as risk factors [12–15]. For elective cases, we routinely use bowel preparation. The other identified parameters were irrelevant to our strategy development as these factors are difficult to be control. Because in 2004, in three out of four resections that resulted in leaks, a single-layered, continuous, transmural, seromuscular anastomotic suture was used, we abandoned this technique despite its wide acceptance. Controlling the strategy implementation rate by looking through the operative notes has shown a compliance of 98% to 100% for using the recommended anastomotic suturing technique. However, there was no improvement in the insufficiency rate in the year 2005. As a result, we standardised the evaluation of the blood supply to the anastomotic site as an absolute requirement. Furthermore, the experience of the surgeon may be important [16]. Therefore, only two surgeons were allowed to perform the rectal resections since 2007. In the following years, a continual improvement of the anastomotic leak rate has been achieved. However, it should be noted that previous publications have found that surgeon experience had no influence on major complications [17] or anastomotic leakage rates [18].

Strategy implementation

Communication and control of the strategy is the basis for strategy realisation. In our case, the implementation of the strategy was achieved using a checklist given to all medical doctors. The content of the checklist was reviewed during the M&M meetings and in every staff appraisal. The strategy implementation was controlled by reviewing the theatre notes, patient records and the daily ward notes. Controlling the 'blood supply' factor was more difficult than controlling the anastomotic suturing technique. One could postulate that the complete implementation of the strategy of using standardised assessment of the blood supply requires a longer timeframe with regular reinforcement during conferences and teaching sessions. As a result, only after a longer period would a positive effect on the insufficiency rate be seen.

A reason for the delay in the improvement of the anastomotic leak rate could be multi-factorial. However, the analysis of the relevant risk factors did not show a difference in the compared timeframes or were disadvantageous in the second period.

Check

It has been demonstrated that developed strategies for the reduction of anastomotic leak rates have to be continually communicated. Using the M&M meetings as part of the PDCA cycle for quality improvement is a good opportunity to not only theoretically pass on knowledge but to also specifically discuss individual cases with clearly defined responsibilities. Using this method, up to 98% of the surgeons are changing their behaviour in a constructive way [10]. With regard to the prevention of anastomotic leaks, this continual improvement is critical because the incidence is influenced by a lack of avoidance strategies and their communication [19].

Nevertheless, it should be noted that the cause of anastomotic leaks is multi-factorial. However, we found no difference in risk factors such as ASA [20], preoperative radiochemotherapy [21–23], blood loss [21], operative time [21], intraoperative antiseptic conditions [12] or the height of the anastomosis in rectal resections [13, 15, 21–23]. The risk factors of smoking and alcohol abuse [24], immunosuppression [25] and ileus [15] were significantly less pronounced in the first period, whereas we operated on more obese patients [26] in the second period. However, obesity was found to be a risk factor in emergent operations only. The number of emergency operations did not differ between our two study periods.

In rectal surgery, the anastomosis was routinely tested [27], and we did not vary the stapling device during the study period [28]. Furthermore, we routinely used drains and did not change the perioperative care including pain therapy. In particular, we did not use cyclooxygenase-2 inhibitors, which may have a detrimental effect on anastomotic healing [28].

We consider the avoidance of technical and tactical 'errors' to be very important. Using prospective documentation of the performance and the development of strategies for improvement and controlling the strategy implementation is helpful. Our results emphasise the possibility for using the M&M meetings as part of the PDCA cycle for educational purposes and quality improvement.

Conclusion

M&M meetings should be an integral part of training in every hospital. For quality improvement, an open discussion

of every adverse event is necessary. However, in addition, a strategy should be established to avoid these events in the future. Implementation of the strategy must be controlled. This can be accomplished using the PDCA cycle, which can be utilised based on the M&M meeting, and it may lead to quality improvement, e.g. reducing the anastomotic leak rate in colorectal surgery. Therefore, the management tool 'PDCA cycle' should be considered also for medical issues.

Conflicts of interest None.

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