



# Routine prophylactic drainage in rectal surgery—closing the chapter?

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Comment on: Denost Q, Rouanet P, Faucheron JL, *et al.* To Drain or Not to Drain Infraperitoneal Anastomosis After Rectal Excision for Cancer: The GRECCAR 5 Randomized Trial. *Ann Surg* 2016. [Epub ahead of print].

Submitted Nov 10, 2016. Accepted for publication Nov 15, 2016.

doi: 10.21037/tcr.2016.12.76

View this article at: <http://dx.doi.org/10.21037/tcr.2016.12.76>

The discussion about drainage in abdominal surgery is long-lasting: in 1986 a historical perspective was already published, stating that in 1809 the first prophylactic drain was placed into the peritoneal cavity, by the same surgeon that performed the first successful laparotomy (1). Until now, no consensus exists on the routine use of prophylactic drains after rectal surgery. A study in 2011 showed that the routine use of drains after rectal surgery differs significantly between United States and non-United States surgeons, 23% *vs.* 42% respectively (2).

There are several theories to justify drainage of the pelvis after rectal surgery: removal of possible toxic or infectious fluids, hemorrhage or other complications, early detection of anastomotic leakage, or reduce the incidence of anastomotic leakage and pelvic sepsis (3-5). Early detection might prevent additional surgical or percutaneous procedures (6). On the contrary, the routine placement of prophylactic drains is not without risks. Drains have shown to be associated with an increased production of serous fluid, could cause (wound) infections, promote adhesions and could even result in a higher risk of anastomotic leakage (7-9).

In the latest issue of *Annals of Surgery*, Denost and colleagues presented the GRECCAR 5 Randomized Trial (3). In this trial, 494 patients who underwent sphincter-saving resection with anastomosis below the peritoneal reflection, were randomized between a routine, prophylactic pelvic suction drain (n=245) and no drain (n=249). The rate of pelvic sepsis was similar in both arms, 16% in patients with drain and 18% in patients without drain (P=0.58). Rates of reoperation, surgical morbidity and stoma closure were also not significantly different between

both arms. The severity of surgical morbidity according to the Dindo classification and the rate of reoperation was not significantly different between both groups. The authors conclude that the placement of a pelvic drain after rectal excision for rectal cancer does not have any beneficial effect for patients, and claim that this study should bring an end to the controversy regarding the routine use of a pelvic drain after a low anterior resection. We congratulate the authors and appreciate that they were given the opportunity to publish a trial that was not able to reject the null hypothesis in *Annals of Surgery*.

We fully agree with the conclusion of Dr. Denost and his colleagues. In the past two decades, many studies were published on the routine use of prophylactic drains in patients who underwent colorectal surgery. There has not been one single randomized study that showed a benefit for the routine use of a prophylactic drain in rectal surgery (9). Five meta-analyses have been published on this topic so far, the first in 1999 and the latest was recently published (4,6,9-11). All previous meta-analyses have concluded that there was no evidence that justifies routine drainage of colon or rectal anastomosis and large randomized clinical trials are warranted (4,6,9-11). Almost 20 years ago, in an editorial letter in 1999, it was already clearly stated that there was no place for drainage in uncomplicated colorectal surgery (12). Interesting enough, all studies that have been published afterwards did not show any beneficial effect of drainage after rectal surgery and now the GRECCAR 5 trial, the largest trial so far, also reported negative results.

The most recent meta-analysis of Zhang *et al.* (published before the GRECCAR 5 trial) studied the effect of

prophylactic drain placement in patients with colorectal anastomosis in 11 randomized clinical trials (9). The meta-analysis did not show any statistical differences in 1,803 patients with and without routine prophylactic drain placement with regard to overall anastomotic leakage, clinical anastomotic leakage, radiological anastomotic leakage, mortality, wound infection, reoperation and respiratory complications. Stratification at the site of the anastomosis (intra- and extra-peritoneal) or type of drainage (active and passive) did not show different results. No publication bias was detected.

The debate about routine, prophylactic drainage originally started in colorectal surgery overall. The first studies focused more on colonic anastomosis and did not find any beneficial effect of drainage (9,13). Opposite to colonic anastomosis, the risk of anastomotic leakage is higher in rectal surgery because there is no nearby peritoneum or omentum with the known protective and absorptive characteristics (8,13). When seroma or hematoma develops in the presacral space, this can be an excellent medium for bacteria (14). Therefore, more recent studies focused on rectal surgery.

With the introduction of total mesorectal excision (TME) the technique of rectal surgery improved, enabling more low anterior resections where previously abdominoperineal resections were performed. In the time period where TME surgery was introduced, the rate of abdominoperineal resections decreased from 55–60% to 27% (15). With this improvement, more primary anastomosis were created, resulting in more patients at risk for anastomotic leakage (16). This observation made prophylactic measures to prevent anastomotic leakage more urgent (3). An observational study of Peeters *et al.* in the population of the TME-trial itself, showed that the risk of anastomotic leakage was lower when a drain was placed: 9.6% anastomotic leakage was observed in the group of patients where a drain was placed, *vs.* 23.5% patients without a drain (14). Mortality between groups of patients with and without drains and with and without diverting stomas were not significantly different but the rate of surgical interventions was lower in the group of patients with a diverting stoma and the drainage group.

There have been more studies with an observational nature where it was found that patients where a drain was placed have a lower anastomotic leakage rate (6). In these observational studies the patients only received a drain when the surgeon found that a drain was indicated. These results were confirmed in a meta-analysis of Rondelli *et al.*, a meta-analysis where not only randomized controlled trials were

analyzed, but also observational studies (6). The authors of the meta-analysis state properly in the discussion that when surgeons find a drain indicated, this decision is mostly based upon personal experience of the surgeon and the occurrence of perioperative complications, such as hemorrhage or technical difficulties when creating the anastomosis. In these observational studies a favorable outcome for drains was reported even though the a-priori risk of an anastomotic leakage was considered to be elevated (6). In our opinion this illustrates the fact that routine placement of drains in patients undergoing rectal surgery is not indicated, but advised when the surgeon considers the risk of anastomotic leakage to be increased e.g. in case of perioperative hemorrhage. Additionally this illustrates the point of view that a drain is able to decrease the risk of anastomotic leakage when indicated.

Regarding the trials that were analyzed in previous meta-analyses, there are still some underexposed aspects. The moment of randomization (before or after surgery) has never been discussed, but varied between trials. In the GRECCAR 5 trial, the patients were randomized the day before surgery. As a result of that, two patients were randomized for a prophylactic drain but a drain was not placed when surgery was finished, and vice versa for 27 patients randomized to no drain. The trial was analyzed according to intention to treat (3). In other trials, patients were randomized after the completion of the anastomosis (8,13).

Another aspect that was not reported consistently was the rate of diverting stomas that were constructed and the indications for this (e.g., standard procedure for anastomosis below 6 cm from the anal verge, or to the preference of the individual surgeon) (3,6). Randomization before surgery could hypothetically have influenced the rate of constructed diverting stomas between the arms. The construction of diverting stomas is associated with a decreased risk of anastomotic leakage, and therefore the surgeon could have been influenced by the outcome of the prior randomization (17). Because the individual trials have not always reported the numbers nor the outcomes of patients with diverting stomas, it is not possible to draw conclusions with regard to the association in patients with or without diverting stomas and the routine placements of drains. Hypothetically it could be possible that the construction of a diverting stoma is sufficient for the prevention of clinical anastomotic leakage and that a prophylactic drain would not further decrease the risk of anastomotic leakage. Ironically, in the RECTODES study, a randomized controlled trial where the construction of a stoma was assigned to patients by

means of randomization, the placement of a drain was to the choice of the surgeon (17).

## Conclusions

To our opinion, with the results of the GRECCAR 5 trial, the debate can finally be closed on the routine use of prophylactic drains in colorectal surgery. Even though some people would consider a new meta-analysis indicated because of this new randomized clinical trial, we would strongly discourage this. The difference between the group with and without drain could hypothetically become significant when including the GRECCAR 5 trial in a meta-analysis, but it is very questionable whether this difference would be clinically relevant. In the GRECCAR 5 trial the difference between the arms is 16% *vs.* 18% anastomotic leakage. If a difference would become significant in a meta-analysis, the Number needed to treat (NNT) would be high.

With the introduction and growing use of laparoscopy, the blood loss per operation has decreased and therefore the indication for a drain is fading (18). Furthermore, with upcoming transanal surgical techniques (TAMIS) and robotic surgery, anastomotic leakage maybe a less common complication in the future. Additional aspects of interest in the future would be the distinction of the effectiveness of drain placement in subgroups of patients with and without a diverting stoma. This would only be the case when the surgeon finds a drain indicated, in the case of excessive fluids such as hemorrhage, or technical difficulties during the construction of the anastomosis.

## Acknowledgments

*Funding:* None.

## Footnote

*Provenance and Peer Review:* This article was commissioned and reviewed by the Section Editor Mu-Xing Li (Department of Abdominal Surgical Oncology, Cancer Hospital, Chinese Academy of Medical Sciences (CAMS) and Peking Union Medical College (PUMC), Beijing, China)

*Conflicts of Interest:* Both authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/tcr.2016.12.76>). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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**Cite this article as:** Frouws MA, van de Velde CJ. Routine prophylactic drainage in rectal surgery—closing the chapter? *Transl Cancer Res* 2016;5(Suppl 7):S1345-S1348. doi: 10.21037/tcr.2016.12.76