

ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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Use and Cost-Effectiveness of Prophylactic Clips Following Colonoscopic Polypectomy



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G&H How significant is the risk of bleeding following colonoscopic polypectomy?

AG According to retrospective data in the literature, the risk of bleeding after colonoscopic polypectomy ranges from 0.2% to 1.2% in patients without risk factors for bleeding. When patients are on blood thinners, such as aspirin or warfarin, this risk has been reported to be as high as 6.8% in some studies. However, these estimates come from variable study designs and patient populations, which is why, in a recent study, my colleagues and I estimated the range to be 2.5% to 3.4% in patients who are on aspirin or anticoagulants.

The risk of postpolypectomy bleeding also depends on other factors, such as removal of large (>1 cm) and/or multiple polyps, a very large defect, and nonsteroidal anti-inflammatory drug use, such as use of ibuprofen. One of the prophylactic methods commonly used by physicians is risk-stratifying patients, particularly in terms of anticoagulant therapy (ie, determining whether patients really need to be on anticoagulant therapy during the procedure and stopping therapy whenever possible).

G&H How effective are endoscopic clips for preventing bleeding following polypectomy (particularly delayed bleeding as opposed to acute bleeding)?

AG There has been much research on gastrointestinal bleeding, whether caused by polypectomy or ulcers, and we have very effective therapy to treat bleeding, from thermal therapy to clips. However, we do not know how well

endoscopic clips work in terms of preventing bleeding after colonoscopic polypectomy. Only a few small retrospective studies published in abstract form have examined the use of clips to prevent bleeding and have shown a reduction in bleeding between 50% and 100%. Prospective, full-length studies are needed to determine how well clips reduce the risk of postpolypectomy bleeding.

G&H What are the advantages and disadvantages of using prophylactic clips?

AG The advantages are that clips can be placed during the procedure itself and, for most trained gastroenterologists, are fairly easy to deploy (particularly for routine polyps, such as 1-cm polyps) and do not appear to add a significant amount of time to the procedure. In addition, clips do not appear to have significant long-term complications, such as scarring.

The disadvantages are that the clips add to the cost of the procedure (particularly if multiple clips are used), which is passed on to the patient, and clips may be used when they are not actually needed. In addition, when adding a clip—or any device—there is a risk that perforation may occur or that it may cause additional bleeding, although this is not common.

G&H When should prophylactic clips be used in patients?

AG Based on the available data from retrospective studies, it is reasonable to use prophylactic clips in patients who are on anticoagulant therapy that cannot be stopped

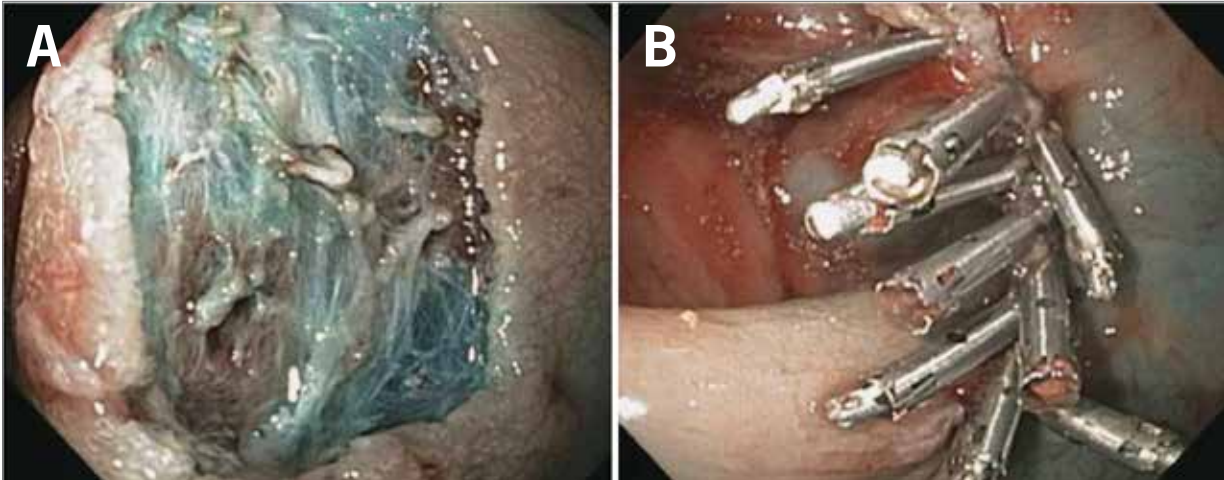


Figure 1. A large polypectomy defect (A) closed with multiple clips (B).

Images courtesy of Rajesh N. Keswani, MD, Northwestern University Feinberg School of Medicine, Chicago, Illinois.

and in whom a large polyp is being removed (Figure 1). If clips work most of the time to prevent bleeding (eg, if there is an 82% risk reduction), then it is also likely cost-effective to use clips; therefore, based on the literature of bleeding risk after polypectomy, it is likely cost-effective to place clips in patients on anticoagulant or antiplatelet therapy. Because patients not on anticoagulation or antiplatelet therapy have an already low bleeding risk, routine placement of prophylactic clips after polypectomy does not appear to be cost-effective. When removing a polyp that is 1 cm or less in a patient who is not on anticoagulant therapy, an endoscopic clip does not necessarily need to be placed. However, if the polyp is very large (2 to 4 cm), even if the patient is not on anticoagulant therapy, most endoscopists would probably want to close the defect to prevent postpolypectomy bleeding, even though there is not good evidence to show that this reduces the risk of bleeding in large populations. In this case, the endoscopist would probably use as many evenly spaced endoscopic clips as needed to completely close the defect.

G&H How exactly can the cost-effectiveness of clips be determined?

AG My colleagues and I built a Markov model based on retrospective data to determine the answer to this question. Essentially, we compared clip placement vs no clip placement following colonoscopic polypectomy, with a base case of a routine colonoscopy in a patient with a 1-cm polyp. The costs that we used were based on our institutional third-party care rates. From the perspective of the medical system—what a third-party insurance payor would reimburse and what a medical facility would get for the clip—a single clip cost \$165 in the model. We found that for patients not on anticoagu-

lant therapy, clip placement did not meet the threshold that is usually set for what is cost-effective (ie, \$100,000 for a quality-adjusted life-year [QALY]). In contrast, for patients on anticoagulant or antiplatelet therapy, using a clip is likely cost-effective.

As cost models are open to bias—because they are based on the quality of estimates used to build the model—sensitivity analyses are performed to test the robustness of the model. For example, in our study, we asked, “What if the clips are really effective, and what if they are really cheap?” If we assume that the clips are 100% effective, then they are pretty much always favorable when patients are on anticoagulant or antiplatelet therapy (Figure 2). However, if the clips are 100% effective, they are still not cost-effective in patients who are not on anticoagulant therapy (ie, they do not meet the cost-effectiveness threshold of \$100,000/QALY). Therefore, physicians should be wary of placing clips indiscriminately, especially in patients who are not on aspirin or anticoagulants.

However, it is important not to take cost-effectiveness models as first-line evidence (like randomized controlled trials). Cost models allow us to synthesize the known literature, make estimates on the effectiveness of a current intervention, and think about why an intervention is being done; cost-effectiveness models should not replace clinical judgment. Clips do add to the cost of a procedure, so if they are not providing a benefit, such as reducing the risk of bleeding, or if there are no real data to support their benefit, use should be judicious.

G&H How do these findings compare with those of other studies and models?

AG There have not been other studies on the cost-effectiveness of prophylactic clip placement to reduce the

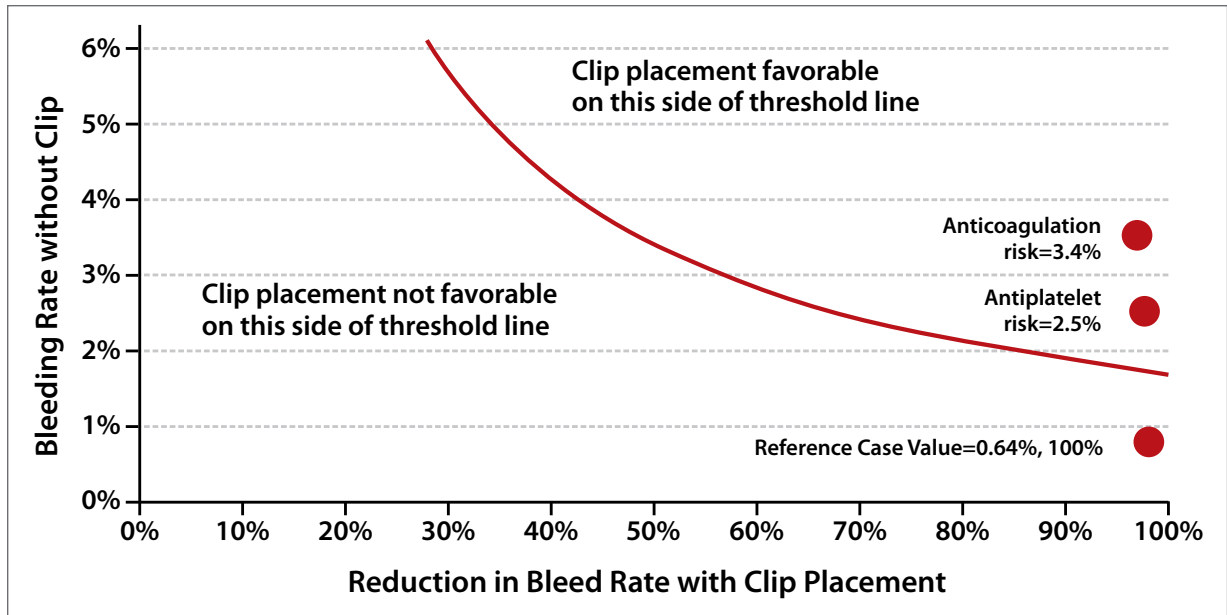


Figure 2. Two-way sensitivity analysis of reduction in bleed rate with clip placement.

Adapted from *Clinical Gastroenterology & Hepatology*, volume 11, Parikh ND, Zanooco K, Keswani RN, Gawron AJ, A cost-efficacy decision analysis of prophylactic clip placement after endoscopic removal of large polyps, pages 1319-1324, copyright 2013, with permission from Elsevier.

risk of bleeding after colonoscopic polypectomy, which is why my colleagues and I conducted our study. We think our model provides a rationale for a randomized controlled trial or prospective study to further evaluate this issue. We suspect that clips are frequently being used in clinical practice after polypectomy, but there needs to be better evidence to support this use. Endoscopists should be aware of the different scenarios of when placing a clip may not be cost-effective and remember that no matter how easy the device is to place, it still costs money. One endoscopist placing unnecessary clips would have a negligible impact, but if thousands of endoscopists are placing thousands of unnecessary clips, it could lead to significant increased costs for patients and the healthcare system.

G&H With the increasing use of novel antiplatelet and anticoagulant agents, do you anticipate that endoscopic clip placement will be used increasingly during colonoscopy?

AG This is an interesting question and a good area for future research, as there are certainly many new antiplate-

let and anticoagulant agents emerging. I anticipate that the use of endoscopic clips would potentially increase accordingly. However, to definitively know if this is true, an actual study is needed on the trends of endoscopic clip placement at the time of colonoscopy.

Dr Gawron has no relevant conflicts of interest to disclose.

Suggested Reading

Katsinelos P, Fasoulas K, Chatzimavroudis G, et al. Prophylactic clip application before endoscopic resection of large pedunculated colorectal polyps in patients receiving anticoagulation or antiplatelet medications. *Surg Laparosc Endosc Percutan Tech.* 2012;22(5):e254-e258.

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