

# Patients' willingness to defer resection of diminutive polyps: results of a multicenter survey

## Authors

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## Bibliography

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 Appendix e1

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## ABSTRACT

**Background and study aims** Current colonoscopy practice requires removal of diminutive polyps. This is associated with costs, but the benefits to colorectal cancer (CRC) prevention remain unclear. The study aim was to understand patients' willingness to defer resection of diminutive polyps and to examine the factors that influence patients' decisions.

**Patients and methods** Adults presenting for a colonoscopy were surveyed at three hospitals in the USA and Canada. Survey domains included: patient characteristics, risk perception, knowledge about CRC risk, willingness to defer polyp resection, and associated concerns. The primary endpoint was the proportion of patients who would be willing to participate in a clinical trial that deferred resection of diminutive polyps. Secondary endpoints included factors associated with willingness to defer diminutive polyp resection.

**Results** 557 eligible individuals completed the survey (mean age 63; 61% men), with 50% of respondents being willing to participate in a randomized trial in which resection of diminutive polyps would be deferred until the next surveillance colonoscopy (95% confidence interval [CI] 46%–55%). Outside of a clinical trial, 57% of participants would be agreeable to deferring resection of diminutive polyps (95%CI 51%–63%). Willingness to defer diminutive polyp resection was associated with higher education ( $P=0.001$ ), greater knowledge about cancer risk ( $P=0.002$ ), and a lower perception of cancer risk (all  $P<0.001$ ). Age, sex, income, a history of polyps, and a first-degree family member with CRC were not associated with willingness to defer diminutive polyp resection.

**Conclusions** More than half of individuals undergoing a routine colonoscopy would be agreeable to deferring resection of diminutive polyps and participating in a trial to evaluate this approach.

## Introduction

The effectiveness of colonoscopy is based on the detection and removal of precancerous polyps [1–3]. Current colonoscopy practice is to remove all polypoid lesions irrespective of their size or appearance. Most polyps are diminutive and approxi-

mately half of these are hyperplastic polyps and not cancer precursors [4]. Although the other half are adenomatous polyps and by definition dysplastic, they very rarely harbor or progress to cancer [5–8]. Studies evaluating polyp progression have shown a very slow growth of small polyps without increased risk of cancers within surveillance intervals [6].

One recent longitudinal study examined the growth rate of diminutive polyps that were not resected and found a mean size progression of 0.6 mm after a mean of 7.8 years of follow-up [9]. Another study using computed tomography (CT) colonography determined that ignoring diminutive polyps was safe and cost-effective. By applying a Markov model to a hypothetical cohort, this study concluded that removal of diminutive lesions would carry an unjustified burden compared with the minimal gain in clinical efficacy [10]. These findings are reflected in the CT colonography guidelines, which support a non-resection approach for diminutive polyps unless growth is detected at the subsequent surveillance examination [11–13].

The concept of deferring resection of diminutive polyps is currently only applied in the context of screening with CT colonography or colon capsule endoscopy. Although the technology is different from colonoscopy, the same goal applies to all three tests—to detect and remove neoplastic lesions to reduce incident cancers and, by doing so, reduce colorectal cancer (CRC) mortality. However, it is plausible that the colonoscopy practice of removing all diminutive polyps also represents unnecessary overtreatment, because these lesions may never progress to a cancer stage within the individual's lifetime [6, 13–15].

Deferring polyp resection would lead to cost saving, both from reduced pathology and equipment costs. It can be assumed that cost savings would be greater than with “resect-and-discard,” which has been estimated to provide annual net savings of over \$730 million [16]. These cost savings are primarily based on the decreased need for pathology evaluation as a US study found that the cost for a colonoscopy without polypectomy is \$1000, while the cost of colonoscopy with polypectomy and pathology is \$1500 [17].

Because cancer in diminutive polyps is exceedingly rare and the use of image-enhancing techniques can usually identify the presence of advanced histology in diminutive polyps, a discussion about adopting the practice of diminutive polypectomy deferral seems warranted [4, 7, 18, 19]. To determine whether deferring resection of diminutive polyps during colonoscopy is safe and does not increase cancer risk requires a large prospective trial. Given current endoscopy practice, it is unclear how patients would respond to the idea of deferring resection of diminutive polyps and whether they would be willing to participate in such a study. We conducted a survey to evaluate patients' willingness to defer resection of diminutive polyps and the factors associated with this decision.

## Patients and methods

### Study design and population

We conducted a cross-sectional survey study at three academic medical centers (Montréal University Hospital Center, Montréal, Québec, Canada; Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA; Department of Veterans Affairs Medical Center, White River Junction, Vermont, USA).

Study participants included adults aged 50–80 who were scheduled for an elective colonoscopy with a potential polyp resection, including screening, surveillance, or diagnostic colo-

noscopies. Survey participation was offered to individuals in the waiting area before their scheduled colonoscopy procedure at the US centers. Eligible participants at the Canadian center included those who had already agreed to participate in a different colonoscopy trial related to bowel preparation (NCT02547571) and such patients were offered the opportunity to complete the survey during a clinical outpatient visit related to the planned colonoscopy. Based upon medical history review, those patients with inflammatory bowel disease or familial cancer syndrome (known or suspected familial adenomatous or serrated polyposis syndrome, Lynch syndrome, or attenuated familial adenomatous syndrome) were excluded from survey participation.

The local institutional review boards (IRBs) approved the study.

### Survey content and administration

Before patients completed the survey, we provided them with printed information on colonoscopy, including the harms and benefits (see **Appendix e1**, available online). This material, based upon literature review, contained information on polyps, the general practice of removing them, possible harms and benefits of removing or not removing diminutive polyps, and a figure that related the risk of cancer in a diminutive polyp to other risks, including finding cancer in a larger polyp, having a severe complication during colonoscopy, and lifetime risk of dying in a car accident or being hit by lightning.

The survey included domains on demographic factors, prior screening exposure, risk factors for CRC, knowledge related to CRC screening, attitudes towards harms and benefits regarding removal of small polyps, individual risk perception, and willingness to defer resection of diminutive polyps (see **Appendix e1**, available online). The survey administered at the VA Medical Center did not include the question regarding the willingness to defer resection of diminutive polyps outside of a trial.

The indication for the procedure was completed by the research team at the US centers, but self-completed by the Canadian respondents, which explains the high number with this information missing at this center. To facilitate survey comprehension by respondents, polyps were categorized into “small,” “medium,” and “large” corresponding to the “diminutive,” “small,” and “large” categories that are used in the scientific literature.

### Outcomes

The primary outcome measure was the proportion of individuals who would be willing to participate in a randomized controlled trial in which diminutive polyps (defined as polyps up to 5 mm in size) might not be removed. Study subjects were informed that they would have a repeat colonoscopy predicated upon their initial colonoscopy findings (not more than 5 years later) and that diminutive polyps would be removed if they had grown at the time of the follow-up exam.

Secondary outcome measures included willingness to not have diminutive polyps removed in clinical practice outside of a study. We further examined factors that were associated with willingness to defer resection of diminutive polyps, includ-

ing perception of cancer risk, attitudes towards harms and benefits of colonoscopy and polyp resection, demographic factors, and family history of CRC.

## Analysis

We used a descriptive analysis for the primary and secondary outcomes. Proportions are presented as a percentage with a 95% confidence interval (CI). For comparison of proportions, we applied the chi-squared test or Fisher's exact test, where appropriate. Continuous variables are presented as the mean and standard deviation (SD) if normally distributed. We used the *t* test to compare means. Because we considered a non-adjusted presentation of the data to be most informative, we did not perform a logistic regression analysis. Survey responses were calculated using all completed surveys (numerator) among all eligible individuals who were offered the survey (denominator).

For sample size considerations, we considered that at least 30% of individuals undergoing a screening or surveillance colonoscopy would need to be willing to participate in a potential trial in which resection of diminutive polyps would be deferred to make such a trial feasible. A sample size of 500 would provide a sufficiently narrow 95% CI from 26% to 34%.

The analysis was performed using STATA 11 (StataCorp LP, College Station, Texas, USA).

## Results

### Study cohort

A total of 557 eligible individuals (mean age 63 years; 61% men) completed the survey (response rate 93%) (► **Table 1**). Overall, 51% of individuals presented for a screening colonoscopy, 39% for a surveillance colonoscopy, and 10% for a diagnostic colonoscopy. The majority of subjects (80%) reported having had at least one prior colonoscopy and 47% had a history of polyps; 30% of patients had a family member with CRC, with 19% reporting a first-degree family member with CRC. Overall, 47% had a college degree or higher education.

### Patients' willingness to defer resection of diminutive polyps

Among all respondents, 50% (95%CI 46%–55%) would probably or definitely be willing to participate in a randomized trial in which diminutive polyps would not be removed unless they grew (► **Table 2**). The proportion of patients who would probably or definitely be willing to participate in a randomized trial increased to 57% (95%CI 51%–63%) after excluding subjects who would not want to participate in any clinical research study (*n*=90). Overall, 56% (95%CI 51%–62%) would be willing to defer resection of diminutive polyps in clinical practice if their physician recommended such an approach (► **Table 2**). Respondents who were willing to participate in a clinical trial in which resection of diminutive polyps would be deferred were more likely to agree to defer resection of diminutive polyps outside of a study (*r*=0.53; odds ratio [OR] 11.1, 95%CI 6.4–19.5).

► **Table 1** Characteristics of the 557 eligible patients who completed the survey.

Variables	Patients
Age, mean (SD), years	63.2 (7.8)
Sex, female, n (%) <sup>1</sup>	218 (39.3)
Patient recruitment, n (%)	
▪ VAWRJ	163 (29.3)
▪ DHMC	169 (30.3)
▪ CHUM	225 (40.4)
Prior colonoscopy, n (%) <sup>1</sup>	442 (79.9)
History of polyps, n (%) <sup>2</sup>	259 (46.8)
Reported family history of CRC, n (%) <sup>2</sup>	167 (30.1)
First-degree relative with CRC, n (%)	106 (19.0)
Education, n (%) <sup>3</sup>	
▪ Some high school	35 (6.5)
▪ High school graduate or equivalent	124 (22.9)
▪ Some college	131 (24.2)
▪ College degree	137 (25.3)
▪ Professional degree/Masters degree/PhD	115 (21.2)
Indication for colonoscopy, n (%) <sup>4</sup>	
▪ Screening	202 (50.5)
▪ Surveillance	157 (39.2)
▪ Diagnostic	41 (10.2)

SD, Standard deviation; VAWRJ, Veterans Affairs Medical Center, White River Junction, Vermont, USA; DHMC, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA; CHUM, Montréal University Hospital Center, Montréal, Québec, Canada; CRC, colorectal cancer.

<sup>1</sup> 2 subjects with missing data.

<sup>2</sup> 4 subjects with missing data.

<sup>3</sup> 15 subjects with missing data.

<sup>4</sup> 157 subjects with missing data (146 of these from CHUM).

### Patients' concerns with deferral of diminutive polyps

There were 42% of respondents who were concerned that a diminutive polyp, if not removed, might contain cancer or progress into incurable cancer (► **Table 2**); 15% were afraid to have a higher risk of developing cancer because of a family member with CRC, while 3% were concerned of getting cancer because a friend had been diagnosed with it. Other reasons were mentioned by 7% of respondents, while a full 36% of study participants reported no concerns with leaving diminutive polyps in situ.

► **Table 2** Patients' concerns and willingness to participate in a clinical trial.

Variables	Patients (n=557)
Willingness to participate in a randomized trial in which resection of diminutive polyps might be deferred, n (%) [Response rate 525/557; 94.3 %]	
▪ Definitely YES	59 (11.2)
▪ Probably YES	206 (39.2)
▪ Definitely NO	155 (29.5)
▪ Probably NO	105 (20.0)
Willingness to leave benign-appearing diminutive polyps in place and resect them only at next colonoscopy only if they grew, n (%) [Response rate 348/394; 88.3 %; not part of the VAWR survey]	
▪ YES	196 (56.3)
▪ NO	145 (41.7)
▪ Don't know	7 (2.0)
Concerns related to not removing diminutive polyps, n (%) <sup>*</sup> [Response rate 527/557; 94.6 %]	
▪ None	189 (35.9)
▪ Risk of cancer in polyp or progression into incurable cancer	221 (41.9)
▪ Higher risk of developing cancer because of family history	81 (15.4)
▪ Friend with history of cancer, concerned over getting it too	18 (3.4)
▪ Do not want to participate in a research study	90 (17.1)
▪ Other	39 (7.4)
VAWRJ, Veterans Affairs Medical Center, White River Junction, Vermont, USA. <sup>*</sup> Multiple answers were allowed.	

### Factors associated with willingness to defer resection of diminutive polyps

Higher education was the only examined demographic characteristic that was associated with an increased likelihood of willingness to defer the resection of diminutive polyps, either within or outside of the framework of a clinical trial ( $P=0.01$ ) (► **Table 3**). Age, sex, reported family history, prior history of polyps, and indication for the colonoscopy were not different between respondents who were willing to defer resection and those who were not, either as part of a study or outside of a study. Having had a previous colonoscopy did not affect the decision to defer polyp resection as part of a trial; however, outside of a study, respondents without a previous colonoscopy were more often agreeable to deferring resection of a diminutive polyp than those with a previous colonoscopy (69% vs. 55%;  $P=0.02$ ). Overall, there were no significant differences in responses between the three participating medical centers.

The associations of cancer risk perception and knowledge with willingness to participate in a study in which diminutive benign-appearing polyps were not removed are illustrated in ► **Fig. 1** and ► **Fig. 2**. With increasing levels of perceived risk of cancer in a diminutive polyp, fewer respondents were willing to defer polyp resection ( $P<0.001$ ) (► **Fig. 1**). Similarly, with increased knowledge of the risk of complications during a colonoscopy (information on bleeding, perforation, and death was provided along with cancer risk within a diminutive polyp in the information sheet), the willingness to defer resection of a diminutive polyp increased ( $P=0.002$ ) (► **Fig. 2**). Significant associations were also seen between perception and knowledge of cancer risk and patients' willingness to defer diminutive polyp resection outside of a study (data not shown).

### Discussion

This survey study found that approximately half of patients who present for a routine colonoscopy would be willing to defer resection of diminutive polyps, both as part of a randomized trial and outside of a trial. The biggest concern with deferring polyp resection (stated by 42% of respondents) was the risk of cancer in a diminutive polyp or possible progression to incurable cancer. Not surprisingly, respondents who reported a greater perceived cancer risk were less likely to be willing to defer resection of a diminutive polyp, inside or outside of a clinical trial. In contrast, willingness to defer resection of a diminutive polyp was associated with greater knowledge about cancer risk and having a higher education.

Our study is the first to our knowledge to examine the question of whether patients undergoing a colonoscopy would be willing to defer resection of diminutive polyps. Because resection of each detected polyp is the current standard of care and engrained in colonoscopy practice, we expected that the majority of patients would not support such approach. We were surprised to find that approximately one in every two people surveyed would agree to not removing diminutive polyps when provided with information on possible benefits and harms associated with this practice.

Given the limited nature of healthcare resources, it is important to critically examine interventions that are performed frequently but may provide little (or even no) benefit. Diminutive polyp resection might be such an intervention because the effects on CRC prevention are likely to be very limited and might not justify the costs associated with this practice. Cross-sectional colonoscopy studies suggest that the risk of finding cancer in a diminutive polyp is approximately one per 2000–3000 polyps [4, 7, 19]. A more recent and larger study has indicated that the risk might even be much lower. Among more than 42 000 diminutive and small colorectal polyps (<10 mm), no cancer was found [19, 20].

With respect to progression, the latency phase of diminutive adenomas to transition to cancer is likely to be longer than the lifespan of the individual in most cases. It is estimated that 86% of all adenomas, including non-diminutive adenomas, arising in patients before the age of 65 will never progress to cancer and that only 50% progress to  $\geq 10$  mm within

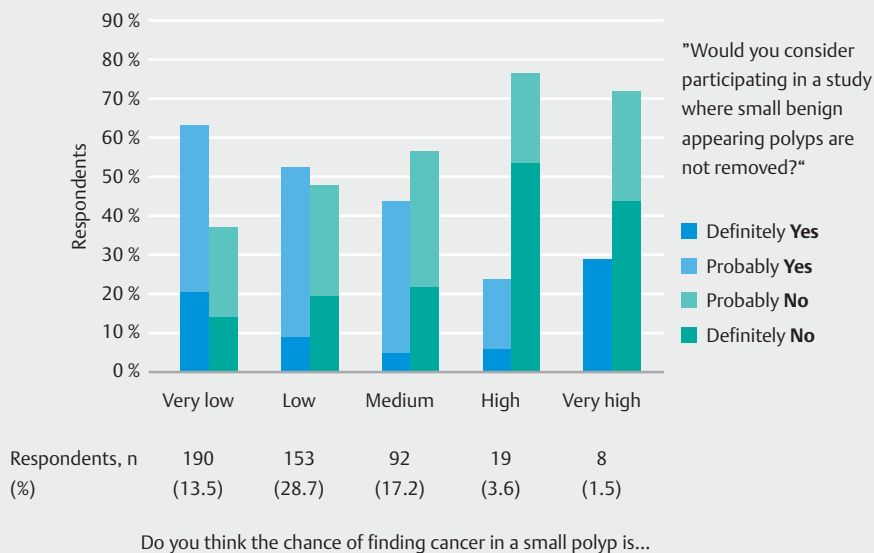
► **Table 3** Characteristics of subjects categorized by their willingness to participate in a study in which diminutive polyps were not removed.

Variables	Probably/ definitely Yes	Probably/ definitely No	P value
Patients	265	260	
Age, mean (SD), years	62.7 (7.6)	63.5 (7.9)	0.25
Sex			0.43
▪ Women (n = 321)	52.0%	48.0%	
▪ Men (n = 202)	48.5%	51.5%	
Center			0.57
▪ VAWRJ (n = 157)	53.5%	46.5%	
▪ DHMC (n = 166)	47.6%	52.4%	
▪ CHUM (n = 202)	50.5%	49.5%	
Education			0.001
▪ Some high school (n = 28)	32.1%	67.9%	
▪ High school graduate or equivalent (n = 114)	41.2%	58.8%	
▪ Some college (n = 126)	49.2%	50.8%	
▪ College degree (n = 133)	55.6%	44.4%	
▪ Professional/Masters degree/PhD (n = 113)	61.1%	38.9%	
Reported family history			0.55
▪ Yes (n = 158)	50.6%	49.4%	
▪ No (n = 308)	53.6%	46.4%	
First-degree relative with CRC			0.51
▪ Yes (n = 99)	47.5%	52.5%	
▪ No (n = 426)	51.2%	48.8%	
Prior colonoscopy			0.31
▪ Yes (n = 420)	51.7%	48.3%	
▪ No (n = 104)	46.2%	53.8%	
Reported history of polyps			0.46
▪ Yes (n = 246)	53.3%	46.7%	
▪ No (n = 120)	49.2%	50.8%	
Indication for colonoscopy			0.77
▪ Screening (n = 200)	51.5%	48.5%	
▪ Surveillance (n = 153)	48.4%	51.6%	
▪ Diagnostic (n = 39)	53.8%	46.2%	

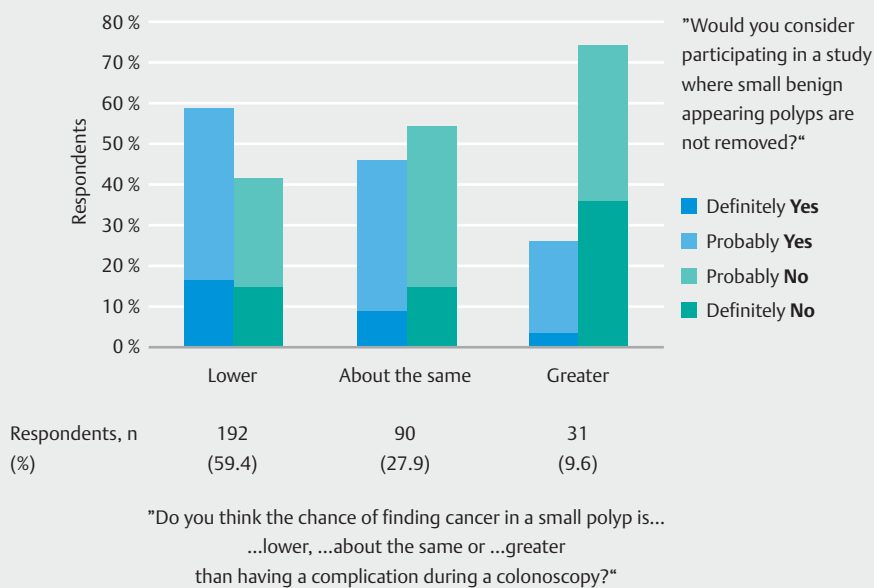
SD, Standard deviation; VAWRJ, Veterans Affairs Medical Center, White River Junction, Vermont, USA; DHMC, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA; CHUM, Montréal University Hospital Center, Montréal, Québec, Canada; CRC, colorectal cancer.

the carrier's lifespan [6, 9, 21, 22]. Studies using CT colonography for CRC screening have demonstrated that the majority of polyps of 6–9 mm (65%–78%) exhibit no growth within 2–3 years and concluded that deferring diminutive polyp resection is safe within 5-year intervals [14, 15].

While such an approach is not endorsed for colonoscopy practice in Europe and North America, the American College of Radiologists supports a watchful waiting approach in their recommendations on CT colonography screening and the Japanese Society of Gastroenterology (JSGE) endorsed such an ap-



► **Fig. 1** Perception of cancer risk in diminutive polyps and willingness to participate in a study in which diminutive benign-appearing polyps were not removed.



► **Fig. 2** Knowledge about cancer risk in diminutive polyps compared with the risk of a complication during a colonoscopy and willingness to participate in a study in which diminutive benign-appearing polyps were not removed. Note: respondents were given information on both risks with the survey.

proach in their 2014 practice guidelines for the management of colorectal polyps [11, 23, 24]. The JSGE guidelines recommend not resecting diminutive polyps, with the exception of diminutive flat and depressed lesions that are difficult to distinguish from adenomas or carcinomas [24].

Other important aspects of introducing the concept of diminutive polyp deferral are patient anxiety and medicolegal issues. Leaving polyps in situ may cause patient anxiety and it will

be important to provide adequate information on both risk and benefit to the patients in this circumstance. Specifically, the small risk of cancer from leaving lesions in situ vs. the small risk of complications when polyps are removed will need to be presented in an intelligible way — often to individuals who do not find numbers or statistics easy to understand.

The low but existent procedural risk with polyp resection should not be ignored. The immediate bleeding rate for resec-

tion of small and diminutive polyps is 0.5%–2.2%, while delayed bleeding occurs in 0.3%–0.6% of cases [25–30]. For diminutive polyps the risk of perforation is low, especially when cold forceps or cold snare polypectomy is used [25,31–33]. Perforation as a result of polypectomy for diminutive polyps is usually associated with using electrocautery (hot biopsy forceps or snare) [33]. The risk of post-polypectomy syndrome is 0.009%, and the risk for perforation in larger study cohorts is between 0.02% and 0.09%; however, because of the low overall incidence of perforation, it is difficult to establish exact numbers for diminutive polyps from the published data, but perforation rates for resection (even if small) will likely be higher compared with deferring resection [34,35].

With regard to potential medicolegal issues, such an approach would require endorsement of governing societies. A recent survey among gastroenterologists found that 72% of gastroenterologists would agree to defer resection of diminutive polyps if such an approach was endorsed by governing societies [36,37]. Interestingly, the study further reported that many gastroenterologists do not resect diminutive polyps if the polyp appearance suggests non-adenomatous tissue [36]. Another recent survey study reported that endoscopists were agreeable to not removing diminutive polyps in approximately half of their patients [37]. While the benefit of resecting diminutive polyps for CRC prevention remains unclear, the steadily increasing detection rates for polyps considerably increase the costs of colonoscopy screening programs through resection and histology assessment [4].

Several limitations of our study need to be discussed. The survey was applied to subjects at academic medical centers and willingness to participate in a study might be greater compared with a general practice or community setting (and patients in one site had already agreed to be in a trial). Second, greater than 40% of respondents had a college or higher degree. Considering that higher education was associated with increased willingness to defer resection of diminutive polyps, the generalizability of these results to a wider population may be limited. Third, the survey applied at the VA medical center did not include the question that asked for willingness to defer resection of diminutive polyps outside of a study. However, because the response to both questions at the other two medical centers was similar, we assume that the results to this question would not affect the overall response. Fourth, we did not formally assess how well the information sheet was understood or whether it was read. From informal patient feedback, it appeared that the sheet was easy to read and the survey questions were easy to complete, in addition to it having received IRB approval. One can assume that any information that is given to the patient, particularly from their own physician, will influence their decision as to whether to defer resection of diminutive polyps or not.

Another important issue is that the adenoma detection rate (ADR) is currently an important quality metric for colonoscopy and not resecting diminutive polyps will interfere with its calculation. However, an alternative approach would be to establish the ADR based on optical diagnosis (without resection and histological confirmation). A recent study has shown that is possi-

ble to determine the ADR adequately by photography alone [38]. It is also plausible to establish required ADRs based on >5-mm adenomas or use other metrics such as the rate of advanced adenoma detection instead of the ADR.

The question of whether deferring resection of diminutive polyps until they grow is safe or not has to be answered within a clinical trial. Our results support the feasibility of such a trial with respect to recruitment. The study by Gellad et al. [36] suggests that many endoscopists would be in support of non-resection of diminutive polyps if a clinical trial showed the safety of this approach. A clinical study, in which diminutive polyps were not removed, would also provide valuable data on the natural history of diminutive polyps, as currently growth estimates are primarily derived from mathematical models [6]. Such data would help to better inform current surveillance guidelines and add evidence to current expert and model-driven recommendations [39–42].

Although our data support the feasibility of such a trial, the execution poses challenges. The surveillance interval decision would need to be based on all detected polyps, including those that were not resected. This could be based on real-time optical diagnosis, which has been shown to provide sufficient agreement with pathology-based surveillance intervals [43]. Furthermore, diminutive polyps that have the appearance of cancer (NICE 3) would have to be removed. Therefore, participating endoscopists would need to have expertise in optical polyp diagnosis. Low-risk findings currently allow a 5- to 10-year surveillance interval. For the purpose of safety within such a study, a 5-year interval would be preferable. Complete follow-up would be particularly important and implementation of monitoring and follow-up reminders would be mandatory.

In conclusion, we found that approximately 50% of patients of screening age undergoing colonoscopy would be agreeable to deferring resection of diminutive polyps until the next surveillance colonoscopy and would participate in a randomized trial that evaluated this approach. Our study results suggest that a randomized controlled trial in which resection of diminutive polyps would be deferred is feasible. Willingness to defer resection of diminutive polyps was associated with higher education, lower perceived risk for cancer in diminutive polyps, and greater knowledge of cancer risk. Given that some current screening strategies ignore diminutive polyps, that removing polyps increases procedural risk and cost, and that there is a lack of data to support the benefit of removing all diminutive polyps, a watchful waiting approach of deferring resection of diminutive polyps seems worthy of investigation in a clinical trial.

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## Competing interest

None

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