Colonoscopy Quality Assessment

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Abstract:

Colonoscopy is the cornerstone of colorectal cancer screening programs. There is significant variability in the quality of colonoscopy between endoscopists. Colonoscopy quality assessment tracks various metrics in order to improve the effectiveness of colonoscopy, aiming at reducing the incidence and mortality from colorectal cancer. Adenoma detection rate is the prime metric, as it is associated with the risk of interval cancers. Implementing processes to measure and improve the adenoma detection rate is essential to improve the quality of colonoscopy.

Introduction:

Colonoscopy is the cornerstone of colorectal cancer (CRC) screening programs, whether used as the primary modality or as a follow up to another screening test[1]. Therefore, adequate prevention of CRC relies heavily on colonoscopy.

While studies from the 1990's indicate that colonoscopy could prevent up to 90% of CRC[2-4], more recent studies suggest that the reduction in CRC incidence might be lower, particularly in the right colon[5-9]. Interval CRCs (or post-colonoscopy CRCs) account for 3.4% to 9% of all cases of CRCs and are primarily encountered in the right colon[10-15].

Whereas several factors could contribute to limited effectiveness of colonoscopy[16], data suggest that endoscopist-related factors are the most important element[17-19]. In fact, 71% to 86% of interval cancers can be attributed to colonoscopist-related factors, as they represent missed lesions or result from incompletely resected lesions[20-23].

These concerns have led to an increased emphasis on improving the quality of colonoscopy to maximize its ability to reduce CRC incidence. . The Gastroenterology societies have proposed various indicators of colonoscopy quality[24]. Choosing and measuring the most appropriate metric(s) to assess the quality of colonoscopy for practitioners, and improving them when required, remain a work in progress. This chapter discusses the value and limitations of potential quality metrics and considerations for implementing them in practice to improve colonoscopy performance.

Colonoscopy Quality Process Measures:

The debate continues regarding the ideal quality measure for colonoscopy, as each of the indicators has its advantages and its drawbacks[25, 26]. It is no longer debated though that colonoscopy performance should be regularly assessed for every endoscopist[27, 28]. While adenoma detection rate (ADR) is largely viewed as the best validated practical outcome measure[25-29], two other process measures warrant consideration.

Cecal Intubation Rate:

The use of cecal intubation rate as a quality metric derives from recognizing that colonoscopists should have the ability to perform a complete examination to the cecum in the large majority of procedures[30]. Based on established benchmarks, effective colonoscopists should be able to intubate the cecum in ≥ 90% of all cases, including ≥ 95% of screening colonoscopies in healthy adults[24].

While data from the late 1990s revealed that this benchmark was achieved in only 55% of practitioners in North America[31], more recent evidence suggest improved cecal intubation rates; a study of 10 endoscopists from the University of Maryland found rates ranging between 88% and 97%, except for one endoscopist with a cecal intubation rate of 63%[32]. This study highlights the importance of measuring cecal intubation rates (and similarly other metrics) to identify outliers.

Failure to routinely intubate the cecum is in fact one of the reasons that limit colonoscopy's effectiveness; a study from Japan and another from New Zealand found that interval cancers were due to failure to reach the cecum, in 27% and 54% of cases respectively[33, 34]. Further, Baxter et al found that patients who undergo colonoscopy by endoscopists with cecal intubation rates ≥ 95% were less likely to have interval cancers compared to patients who undergo colonoscopy by endoscopists with intubation

rates < 80% (distal OR, 0.73; 95% CI, 0.54-0.97; proximal OR, 0.72; 95% CI, 0.53-0.97)[12]. Thus, evaluating cecal intubation rates is a first step towards assessing quality colonoscopy.

Withdrawal Time:

Spending sufficient time between intubating the cecum and removing the colonoscope from the patient is necessary to perform a thorough mucosal inspection, with a low miss rate for significant lesions[35]. The suggested benchmark for withdrawal time (WT) is an average of at least 6 minutes in exams where no biopsies or polypectomies are performed (derived from a large number of colonoscopies in patients without prior surgical resection)[24].

The utility of WT as a quality measure has been somewhat disputed, as the evidence is contradictory about its correlation with adenoma or polyp detection rates[19, 36-39]. Recently, the results of a large observational study from England, which included over 31000 colonoscopies, support the value of WT as a quality metric[40]. Colonoscopists with WT less than 7 minutes had significantly lower ADRs compared to those with WT of 11 minutes or longer (42.5% vs 47.1%, p<0.001), with 50% less right-sided adenomas detected per procedure. The authors also found that there was no incremental benefit in ADR beyond 10 minutes of WT (which does not include duration of polyp removal). . Data from a recent abstract by Shaukat et al. suggest that WT might be a more sensitive indicator of interval cancer than ADR[41]. The authors analyzed records of over 76000 colonoscopies performed by 51 gastroenterologists in Minnesota; they found that colonoscopists' average annual WT were inversely associated with interval cancers (p<0.0001), whereas physicians' ADR were not (p=0.40). Compared to WT > 6 minutes, the adjusted incidence rate ratio for WT <6 minutes was 2.3 (95% CI, 1.5-3.4; p<0.0001).

It remains likely though that longer mean WT reflects better withdrawal technique (including cleaning of residual fluid, adequate colonic distention and proper examination of proximal side of folds)[42]. Therefore, colonoscopy experts and the American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology task force recommend the use of WT mainly as a quality indicator for colonoscopists who have low ADR, rather than a stand-alone metric[24, 30].

Adenoma Detection Rate: The Core Outcome Measure:

While it would be most meaningful to measure CRC incidence and mortality, or alternatively the incidence of interval cancers, as actual outcomes of colonoscopy[2], these are not practical for timely quality interventions. Thus, ADR, or the proportion of screening colonoscopies where at least one adenoma is detected, has been proposed as the best, most reliable, and practical surrogate quality metric[24-26]. Current ADR benchmarks are ≥ 25% for men and ≥ 15% for women[24].

ADR Correlation with Risk of Interval Cancer:

Two large colonoscopy studies from Poland and from the US validated the ADR as a quality metric by clearly linking it to the risk of interval CRC[43, 44]. The Polish study was conducted by Kaminski et al between 2000 and 2004[43]. The authors evaluated 45,026 subjects undergoing screening colonoscopy, performed by 186 endoscopists. The results, published in 2010, showed that patients whose endoscopists had an ADR less than 20% were at least 10 times more likely to be diagnosed with an interval CRC, compared with those whose endoscopists had ADR ≥ 20% (p=0.008). Interval cancer risk

increased as ADR decreased, and other than age, all other examined factors did not correlate with the risk of interval cancer.

The US study was carried by Corley et al[44]; the authors reviewed 314,872 screening colonoscopies performed between 1998 and 2010, by 136 high-volume gastroenterologists on patients in the Kaiser Permanente health plan. The results, published in 2014, showed that ADR is an independent predictor of interval CRC, with a Hazard Ratio of 0.52 (95% CI, 0.39-0.69) for patients whose exams were performed by colonoscopists with ADR >33.5%, compared with those whose colonoscopists had ADR <19%. Interval cancer risk decreased linearly with increasing endoscopist ADR, overall and separately in the proximal colon and in the distal colon, and there was no ADR threshold above which there was no further protective benefit; the risk of interval cancer decreased by 3% for each 1% increase in ADR (Hazard Ration 0.97; 95% CI, 0.96-0.98). In addition, the results revealed an inverse association between CRC mortality and ADR: patients who colonoscopists were in the highest ADR quintile had a 62% (95% CI, 35%-88%) reduction in fatal CRC, as compared with patients whose physicians were in the lowest quintile.

ADR Measurement:

Measuring the ADR of every colonoscopist is a priority for colonoscopy quality improvement[24]. It should be noted though that a reliable ADR assessment likely require a large sample size of colonoscopies performed by the practitioner. In a mathematical model developed by Do et al, at least 500 procedures were needed in the ADR calculation to provide narrow 95% confidence intervals, that accurately reflect performance[45].

Nevertheless, ADR is relatively easy to measure, even when it requires manual chart reviews[46]. Despite a somewhat time-consuming process to periodically review pathology data, this is largely facilitated by an objective approach, limited to a binary query, i.e. presence or absence of adenoma- without further characteristics or count. Serrated lesions should not be counted toward the ADR. Added strength of ADR as a quality metric is that it indirectly reflects other factors, including WT, colonoscopist technique and motivation, and bowel preparation quality[47].

The importance of ADR measurement is underscored by the wide rates variability among practicing colonoscopists, ranging from less than 10% to over 50%[17, 36, 43, 44, 48]. The impact of the endoscopist on ADR is substantial, accounting for up to 10-fold difference between colonoscopists, and exceeding the effect of age or gender[17]. The baseline colonoscopy is decisive for effective CRC screening, as it impacts initial clearance from neoplastic lesions, and also dictates subsequent surveillance intervals[30]. Therefore, colonoscopists with high ADR provide their patients with double-protection: more complete baseline clearance, and shorter surveillance intervals. Thus, assessing and improving ADR is at the core of a successful CRC prevention program.

Polyp Detection Rate:

Polyp detection rate (PDR) has received some attention as a surrogate for ADR, as it is automatically collected by colonoscopists while generating procedure reports and/or billing codes, making it more practical to measure than ADR. PDR was validated as a surrogate to ADR by two studies by Williams et al[49, 50]. In the first study conducted at a single academic institution, the authors showed a strong correlation between ADR and PDR (correlation 0.86, p<0.001)[49]. In the second study, which included sixty endoscopists at multiple practice sites, they found again a high correlation between colonoscopists'

PDR and ADR in both men and women (correlation 0.91, p<0.001), as well as a correlation between PDR and advanced adenoma detection[50].

In addition, Baxter et al carried out a large observational study in Ontario, Canada, which showed an association between the PDR and the incidence of interval cancers in the right colon[12]. Patients who underwent colonoscopy by endoscopists with PDR ≥ 30% were less likely to have proximal interval cancers, compared to patients whose colonoscopists had PDR < 10% (OR, 0.61; 95% CI, 0.42-0.89, p<0.0001).

To date, there is no prospective study that evaluates PDR as a quality measure, and there are two main predicaments that can hinder the use of PDR. First, there are no recommended benchmarks from the leading US Gastroenterology societies; potentially, the targets suggested by Williams et al can be used (40% for men and 30% for women- based on correlation with ADR targets of 25% for men and 15% for women, respectively)[49, 50], but these still await official endorsement. Second, PDR is much more prone to corruptibility, by resection of non-neoplastic diminutive polyps or by biopsy of normal tissue; which, as suggested once again by Williams et al, require periodical audits[49, 50]- and these could negate its practicality to some extent.

Adenoma Detection Rate: Limitations:

Expecting colonoscopy to prevent all cases of CRC is unrealistic; however, its effectiveness is based on the ability of endoscopists to detect the vast majority of neoplastic lesions and to remove them completely. While ADR has certainly proven to be a reliable metric of colonoscopy quality, it can be criticized for its inability to gauge if a colonoscopist is leaving behind additional adenomas, other pre-cancerous lesions, or fragments of identified/ resected adenomas.

Adenomas per Colonoscopy:

ADR can overlook differences in colonoscopy quality, as endoscopists with the same ADR could be detecting highly variable numbers of adenomas per colonoscopy[51, 52]. Denis et al analyzed over 42000 colonoscopies performed by 316 endoscopists in France[51]. They evaluated the mean number of adenomas per procedure (MAP, total number of adenomas detected divided by the number of colonoscopies); for colonoscopists with ADR around 35%, the MAP varied markedly between 0.36 and 0.98. Wang et al compared 2 groups of endoscopists, serving the same patient pool in Los Angeles, California, at a tertiary care teaching hospital and at 3 non-teaching facilities[52]. Both groups had fairly similar ADRs (28.8% and 25.7%; p=0.052). The authors assessed the MAP, as well as another suggested metric, the ADR-Plus (mean number of adenomas detected after the first adenoma, in procedures in which at least one adenoma was found). They found that the teaching group had 23.5% higher MAP and 29.5% higher ADR-Plus.

Coupling ADR with another total adenoma metric has therefore been suggested by both previous groups to better assess colonoscopists' performance[51, 52]. Similarly, Lee et al proposed two measures of total adenoma detection to complement the ADR: MAP and MAP+ (mean adenoma per positive procedure, calculated as total number of adenomas detected divided by the number of colonoscopies in which at least one adenoma was detected)[53].

Adding a total adenoma detection metric provides a more comprehensive assessment of the thoroughness of the colonoscopic exam, provides better discrimination between endoscopists and limits potential inclination to "gaming", i.e. a less thorough examination once a first adenoma is detected and resected. However, this makes the assessment much more labor-intensive. Further, this could be an incentive to separate polyps from the same colon segment into different specimen bottles, leading to increased colonoscopy costs. In the absence of formally established benchmarks, and while adherence

to measuring ADR remains far from optimal in routine practice, total adenoma detection metrics will primarily be applied in research settings in the short term.

ADR Benchmarks:

The ADR targets originally defined in 2002 (≥ 25% for men and ≥ 15% for women[24]) may be outdated. Several recent studies revealed ADRs reaching the 40%-50% range or higher in average-risk individuals[40, 44, 48, 53]. Demographic features, other than gender, also affect the prevalence of adenomas[54]; this includes increasing prevalence with age, and more proximal adenomas in blacks compared to whites[55]. As ADR use becomes more prevalent in clinical practice and in different populations, benchmark adjustments will be necessary based on the specific characteristics of the screened demographic group and the most recent ADRs reported in the literature that have been proven to provide cancer prevention.

Advanced Adenomas:

Measuring the advanced ADR might be more clinically relevant, as advanced adenomas are more prone to progress to CRC[56]. Similar to ADR, the is significant variability in advanced ADR between colonoscopists[17, 57]. Among 9 colonoscopists in Indianapolis, detection of adenomas ≥ 1 cm in size varied from 1.7% to 6.2%[17]. Among 14 colonoscopists in Chicago, advanced ADR varied from 2% to 18.18%[57].

This study[57] generated concerns, because it showed that colonoscopists' advanced ADR were independent of their non-advanced ADR (correlation -0.42; 95% CI -0.77- 0.14, p=0.13). In addition, the study by Wang et al[52] showed that the teaching group had a 28.7% higher advanced ADR, compared to

the non-teaching group, whereas ADRs were similar for both groups. These results suggest that some colonoscopists might have adequate ADRs, while missing a significant number of advanced adenomas. These findings warrant future investigation, as they could carry important implications in assessing colonoscopy quality. However, using advanced ADR as a quality metric will likely prove to be very challenging, because of variable polyp size measurement by endoscopists, and large inter-observer variability for villous elements among pathologists.

Serrated Polyps:

An inherent limitation of the ADR is that it does not account for the detection of serrated polyps. This might be problematic as recent evidence suggests that the serrated pathway likely accounts for up to one third of all CRCs[58, 59]. Endoscopic detection of serrated polyps is more challenging than detection of adenomatous lesions, as they are have a subtle, pale appearance and indistinct margins[60]. The prevalence of serrated polyps in the right colon in average-risk patients is higher than previously reported, with a mean of 13% in a recent study by our group[61].

The variability in detecting proximal colon serrated lesions is more striking compared to ADR, ranging from 5 to 18 fold among endoscopists, whereas ADR variation is typically around 3 to 4 fold[38, 62, 63]. In two recent studies, detection rates varied from 1% to 18% among 15 academic gastroenterologists who performed a total of 6681 screening colonoscopies [62], and from 6% to 22% among 5 colonoscopists who completed 1354 screening exams [38].

Interestingly, and despite the variation in detection of proximal serrated lesions, there appears to be a strong correlation between it and ADR[61]. This was the case in both men (correlation 0.71, p= 0.003) and women (correlation 0.73, p=0.002)[61]. Therefore, while not directly capturing serrated polyps, ADR might

still be valid by itself to assess both adenomatous and serrated lesions. This has important practical implications because of several problems impacting the use of serrated polyp detection rate as a quality metric: there are currently no endorsed benchmarks for sessile lesions detection rates; the measurement should only include lesions proximal to the sigmoid colon to avoid the confounding effect of hyperplastic polyps from the rectosigmoid (whereas it is difficult to reliably identify the junction between the sigmoid and the descending colon); and the histological classification of serrated lesions remains challenging and variable in practice[63].

Incomplete Adenoma Resection:

Several studies evaluating interval CRCs found that these cancers can be attributed to incomplete polypectomy in about 10% to 30% of cases[13, 20, 22, 64, 65]. Since ADR is essentially geared at assessing detection and not resection, the inadequate quality in these cases would not be reflected by measuring the ADR. Competent colonoscopists should be able to fully resect most sessile polyps up to 2 cm in size and all mucosally based pedunculated polyps[24].

In the CARE study, Pohl et al assessed the completeness of resection based on 346 polypectomies performed in 269 patients by 11 colonoscopists[66]. Polyps assessed were sessile or flat, ranged from 5 to 20 mm in size, and 59% were in the right colon. The evaluation was based on a biopsy protocol of the margins of the polypectomy site, and revealed an incomplete resection in 10.1% of cases. In addition, there was a wide variability in incomplete resection rate, ranging from 6.5% to 22.7% between endoscopists. Of note, serrated lesions were more likely to be incompletely resected compared to adenomatous polyps (31% vs 7.2%, p < 0.001).

Polypectomy technique and effectiveness is a key component of colonoscopy quality. While awareness is increasing about its variability between colonoscopists, assessing its quality is challenging because it is more difficult than assessing detection quality. However this should not be an absolute deterrent. A group from the UK recently published work to develop and validate a tool to assess polypectomy skills using video reviews[67], but further research is needed..

Implementation of Quality Measurement:

Assessing colonoscopy quality in day-to-day practice should no longer be optional for endoscopists. It is our duty to patients to provide them the best possible prevention against CRC. Measuring competency, and when necessary improving it, can ensure that colonoscopists are held accountable to quality standards.

Process Planning:

The initial step in establishing a colonoscopy quality program is to select the metric that will be assessed[26]. This metric should be measured according to clearly defined parameters, and the measurement method should be precise and consistent. Metrics with well-established benchmarks are likely more useful to gauge performance related to standards. Once the metric and the measurement method are determined, a baseline data collection can be carried out. According to the measurement

results, it can be decided if improvement is required to achieve high value colonoscopy. Repeat data collection will allow to assess the progress.

For endoscopists, the first step in this process is to regularly measure ADR, and if warranted, take action to improve it [68]. Similar considerations apply at the level of an endoscopy center. Hilsden et al shared their process and experience in implementing a colonoscopy quality assurance program at their endoscopy facility in Calgary, Canada[69]. Participation in the quality monitoring program was a requirement to be granted endoscopy privileges at the center. Their program included several aspects, one of which was distribution of report cards to endoscopists, reflecting measurements of their collected indicators, with comparison to the entire group of endoscopists at the center. Metrics reported in the early phase of the program were cecal intubation rate, average withdrawal time and polyp detection rate. Subsequently, the reports included various measures of adenoma detection rate.

On a larger scale, audits can be conducted to assess the quality colonoscopy. In the UK, the results of a 2011 nationwide audit were recently published[70], and included two main quality metrics: cecal intubation rate and polyp detection rate. Compared to the previous audit results from 1999, the cecal intubation rate improved from 76.9% to 92.3%, and the polyp detection rate increased from 22.5% to 32.1%. These examples reflect the feasibility and benefit of implementing colonoscopy quality assessment initiatives.

Resources to Facilitate Implementation:

Quality measurement for colonoscopy cannot be achieved without adequate procedure documentation . It is fundamental to have complete data to accurately measure quality metrics, and standardized electronic reports can facilitate this process. . In 2007, the Quality Assurance Task Force of the National

Colorectal Cancer Roundtable developed a reporting and data system for colonoscopy (CO-RADS) to facilitate quality monitoring within and across practices[71]. Several commercially available endoscopy software programs generate electronic reports that include the elements suggested in CO-RADS.

A group from the Netherlands created a structured colonoscopy reporting system (EndoALPHA) that mandates endoscopists to document various quality indicators, and that automatically generates quality measurement reports[72]. The Clinical Outcomes Research Initiative (CORI) developed a software that captures most of the indicators proposed in CO-RADS[73]. The CORI consortium included 73 practices from 24 states in the United States; they electronically submitted their colonoscopy reports to the database for analysis to measure and improve quality.

The Gastroenterology societies have established two registries to assist individual endoscopists and practice groups in monitoring colonoscopy quality: GIQuIC (GI Quality Improvement Consortium; developed by the American College of Gastroenterology and the American Society of Gastrointestinal Endoscopy) and DHOR (Digestive Health Outcome Registry; developed by the American Gastroenterology Association). Submitting colonoscopy reports to these registries will generate performance reports for gastroenterologists, assessing various metrics, with ADR being the most important.

Natural language processing (NLP) is a medical informatics tool that identifies and extracts information from free-text reports, using artificial intelligence. NLP can retrieve data necessary for colonoscopy quality measurement with high accuracy, specifically adenoma detection metrics[74]. NLP can be helpful in easily quantifying quality metrics for endoscopists, and awaits further study for validation and standardization. .

Interventions to Improve Quality:

Ideally, a colonoscopy quality improvement program should allow identifying underperformers in order to pursue interventions that will improve their performance. The benefit of various interventions is quite variable, and the optimal approach to ameliorate substandard effectiveness is yet to be identified[75].

Withdrawal Time Interventions:

Targeting a longer withdrawal time in colonoscopists with low ADR has been evaluated by several studies. Simply recording withdrawal time did not have a significant effect on increasing overall polyp detection rate[76]. Longer withdrawal time might improve serrated polyps detection rate in the proximal colon[38]. Forcing endoscopists to spend at least 7 minutes on withdrawal did not affect polyp detection rate[77]; this reflects that a forced increase in WT is not spent in effective inspection, when it is not paired with education about withdrawal and inspection techniques.

The most beneficial intervention involving withdrawal time was undertaken by Barclay et al[78]. It started with a group review of optimal inspection techniques, followed by implementation of a segmental withdrawal protocol: at least 2 minutes per colonic segment, indicated by a digital stopwatch beeps; with a total withdrawal duration of 8 minutes minimum. This resulted in a significant increase of the ADR from 23.5% to 34.7% (p< 0.0001).

Educational Interventions:

In Barclay's et al intervention[78], the education component, that preceded the withdrawal protocol implementation, likely played an important role. The Endoscopic Quality Improvement Program (EQUIP) is a recently described educational process[79]. Endoscopists who were assigned to the training (2 sessions: techniques of high quality colonoscopy; and polyps overview and classification) increased their

ADR from 36% at baseline to 47% after training (p=0.0013)- whereas the untrained group ADR remained unchanged at 35%.

Adler et al found that the number of Continuing Medical Education (CME) meetings attended by colonoscopists correlated with their ADR (p=0.012)[19]. The authors suggested that a better understanding of polyp morphology and examination techniques, taught at the meetings, resulted in better colonoscopy performance. Educational programs, whether at local or larger scales, have an important role in improving adenoma detection and resection, as well as recognition and removal of serrated lesions.

Feedback Methods:

In the EQUIP study[79], it should be noted that the training group also received monthly ADR feedback. This might have contributed to the observed benefit. Harewood et al provided quarterly feedback to a group of 58 endoscopists, and noted a 19% decline in incomplete colonoscopies[80]. Lin et al also reported that monitoring and feedback aided quality improvement, with increases in mean withdrawal time and polyp (but not adenoma) detection rate (33.1% to 38.1%, p=0.04)[81]. Implementation of a quarterly report card resulted in a significant increase in cecal intubation rate (98.1% vs 95.6%, p=0.027) and in ADR (53.9% vs 44.7%, p=0.013)[48]; the increment in adenoma detection was mostly due to increased detection of proximal adenomas.

The impact of feedback has not been consistently significant, and several other groups that used feedback interventions reported negative results[75]. Shaukat et al applied a series of systematic interventions over a 3-year period, including feedback and educational programs, but were not successful at improving endoscopists' ADR[82].

Video-monitoring:

Rex et al assessed the impact of video recording on the quality of colonoscopy performance[83]. Endoscopists' awareness of the recording resulted in 49% increase of mean inspection time, and 31% improvement in mucosal inspection technique. Whether this improves ADR remains to be seen, but Madhoun et al recently reported that video recording was associated with a non-significant increase in ADR (while hyperplastic detection increased significantly)[84].

Researchers at the Mayo Clinic created an Endoscopic Multimedia Information System (EMIS) which involves recording, monitoring and assessing colonoscopies[85]. The system is being developed to allow real-time analysis and as needed feedback related to routine colonoscopy maneuvers, in order to achieve high quality with each colonoscopy.

Video-monitoring or advanced automated assessment systems could prove valuable to complement the current interventions used to enhance colonoscopy quality, especially that many of these interventions have limited effectiveness.

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