Author's response to reviews

Title: Capsule Colonoscopy Increases Uptake of Colorectal Cancer Screening

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Version: 3 Date: 11 May 2012

Author's response to reviews:

Dear Editors,

We thank you very much for giving us the opportunity to revise our paper and we much apologize that we introduced some delay. Below you will find our replies; we think that the paper is now improved and hope that it might be acceptable for your journal

Best regards on behalf of the coauthors

Thomas Rösch

Reply to Reviewers

Reviewer 1

We thank the reviewer for his thoughtful comments which were certainly of great help to improve the paper

Summary:

Investigators in Germany tested the hypothesis that an offer of capsule endoscopy through a major regional insurer, would increase the uptake of CRC screening. Enrollees were offered description of pros and cons of capsule colonoscopy (CC) and conventional optical colonoscopy (OC), with an offer to undergo either test. Capsule was preferred by a 3:1 margin over OC. A large number of invitees evidently underwent OC outside the scope of the program, so the effect of the invitation was uncertain in this group. Adenoma detection rate
(by patient) was 26% in OC group and 9% in CC group. A survey was used to identify bases for user preferences and post hoc satisfaction.

Critique:
This study marks an interesting addition to the armamentarium of approaches taken to foster CRC screening, and likely the first to compare patient uptake of CC when offered as an alternative to OC. The greater preference for CC in men is perhaps not surprising and a consideration that could be used to leverage greater screening participation, especially in men.

Limitations of the study are several, but nonfatal. There was an overall rather low overall response rate, though likely not much lower than observed in other similar trials.

Reply: We agree that the response rate was low, but also during opportunistic screening in Germany, the spontaneous uptake in this area (1%) was lower than on German average (3%). We added a comment with respect to this limitation in the Discussion, now point 1, p. 7

An effort to reach nonresponders to assess their reasons for nonparticipation would have been helpful.

Reply: Due to data safety restrictions we could not analyze these data outside of the reach of the medical insurance; the cooperation insurance company was hesitant to bother their customers a second time. A comment was added in Methods p. 4

Of the 15 with technically unsatisfactory CC (“incomplete”), 6 underwent OC. The difference in adenoma rate of 26% vs 9% in the OC vs CC groups was described as nonsignificant. This is actually a fairly dramatic difference, with a nonsignificant outcome likely due to sample size. Authors might wish to comment on this.

Reply: The study was powered for acceptance, not for adenoma yield as we mentioned in the Discussion. We therefore did not calculate significance; in fact using Fishers exact test, these differences were significant, which is now included in Results p. 6, 4th para

A high proportion of polyps found on CC were >1cm, whereas the OC-detected tended to be smaller. One tends to assume this discrepancy may be due to relative insensitivity of CC for subcentimeter polyps. A comment about this would be worthwhile.

Reply: The reviewer is probably correct, this was also our assumption, although the power of the study was not enough to prove this. We added a comment including the speculation about improved sensitivity with newer capsules in the Discussion on p. 8
The authors do comment on the logistic challenges of following a CC positive screen with OC in a timely enough way as to avoid reprepping the patient. It would be helpful if the authors could comment on how explicitly this need to reprep was explained to subjects, including the fact that this would be a needed undertaking in about 5-20% of cases that would be positive or incomplete.

Reply: In contrast to most previous trials, in which capsule findings were not known at the time of colonoscopy which served as gold standard, capsule results did influence the performance of colonoscopy in our study. Unfortunately, we could not provide the logistics for quick capsule reading to have positive capsule and ensuing colonoscopy with one colon preparation. This was mentioned in the standardized informed consent to patients. Remarks were added to Methods, p. 4 and to the Discussion p. 9, 2nd para.

The combination of (apparent) insensitivity for polyps <1cm with CC and relatively high rate of repeat CC would be thought to have accounted for a lower proportion of CC uptake. Authors may wish to comment on this as well.

Reply: The reviewer is probably correct, although it is difficult to judge to which extent screenees were aware of the full implication of this fact. We added a comment to the Discussion, p. 9, 2nd para.

Reviewer 2
We thank the reviewer for his suggestions which we gladly used for correction of our paper.

Minor essential revisions: misspellings on p 4

Reply: Corrected

Discretionary revisions:
1.) Make a comment about any possible bias introduced by focusing only on one group covered by a single insurance carrier (economic diversity, tendency to utilize health care resources, etc.)

Reply: A comment was added (p. 8, 2nd para).

2.) Comment on possible impact of free capsule on opportunity to participate in screening as this would not reflect real world circumstances of screening.

Reply: Naturally, screening behavior would be different in setting with free access to the respective screening test versus self-paid methods; since colonoscopy is reimbursed over the age of 55 (without colonoscopy in the preceding 10 years), we think that free access to capsule colonoscopy allowed for a fair comparison in the German setting. Naturally, this would change with changing reimbursement strategies. This comment was added to the Discussion, p. 8, 3rd para.
3.) p 8, Revise comment speculating sensitivity of capsule colonoscopy. do not state an estimated percentage, simply state that under routine conditions the sensitivity may be expected to be lower.
Reply: We changed the text accordingly (p. 8/9).

Editors Comments

- kindly change "Introduction" Section into "Background," thanks.
Reply: done

-Conclusions:
This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.
Reply: We tried to make the abstract conclusions better understandable