Author's response to reviews

Title: Comparative cost-efficiency of the EVOTECH Endoscope Cleaner and Reprocessor versus manual cleaning plus automated endoscope reprocessing in a real-world Canadian hospital endoscopy setting.

Authors:

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Version: 3 Date: 4 May 2011

Author's response to reviews: see over
Dear Editor,

Please find enclosed our revised manuscript with revised title “Comparative cost-efficiency of the EVOTECH Endoscope Cleaner and Reprocessor versus manual cleaning plus automated endoscope reprocessing in a real-world Canadian hospital endoscopy setting”.

We thank all of the referees for their important feedback. We feel the suggested changes have improved the paper. To the best of our ability, we have accommodated the referees’ requests for revisions. Where revisions were not incorporated, we have provided some explanation below.

In addition to the marked changes in the abstract, some text was removed in order to shorten the abstract to the required 350 word maximum.

Referee 1.

Comment 1: “The manuscript states: “Due to the increased manual wear and tear on endoscopes with manual brushing, scopes would have to be replaced and/or repaired more frequently.” “The authors are respectfully asked to include a reference in the manuscript documenting this statement’s validity.”

Author Reply: References have been added to the manuscript.

Comment 2: “The authors of this manuscript are respectfully asked to explain why for the Evotech device (and the Medivators device) the median time required to reprocess colonoscopes (37.42 minutes) listed in Table 2 was longer than to reprocess bronchoscopes (36.04 minutes). Might this difference be due to the physical complexity of the former and the relative simplicity of reprocessing the latter? Moreover, the authors of this manuscript are respectfully asked to explain why the difference in the time required for the Evotech and the Medivators devices to reprocess colonoscopes is significantly greater (12.46 minutes) than for reprocessing bronchoscopes (5.66 minutes).”
Author Reply: The reviewer is correct in that the time required to reprocess colonoscopes is longer because of the complexity of the colonoscopes where there are three channels to manually brush in the colonoscope and only a single channel in the bronchoscope. No change was made to the manuscript to explain this. It is assumed that readers of the paper would be aware of the physical differences between the endoscope types.

Comment 3: “The manuscript’s page 4 states: “As a result, the SGNA states that, ‘inadequate cleaning of endoscopes has been one factor cited in transmission of infection by flexible endoscopes.’” The authors are asked to supplement this reference by including another citation to a clinical report that linked inadequate cleaning of GI endoscopes or another type of flexible endoscope to disease transmission.”

Author Reply: Thank you. The two examples of references for patient-to-patient transmission of infection were added to the manuscript.

Comment 4: “The manuscript’s page 5 states that the Evotech reprocessing system is the first system to both clean and high-level disinfect endoscopes. The authors are respectfully asked to clarify and modify the text to be more accurate. Although the Evotech is indeed the first (and, to date, only) device cleared by the FDA to eliminate manual pre-cleaning of the endoscope prior to its automated processing, it is not the first device used in Canada or cleared by the FDA as a “washer-disinfector.” Other devices prior to the commercial distribution of the Evotech have been available for cleaning and high-level disinfecting endoscopes (but not for eliminating manual pre-cleaning of the endoscope).”

Author Reply: We have clarified in the manuscript that the EVOTECH ECR received FDA approval for the elimination of manual pre-cleaning prior to its automated processing.

Comment 5: “The authors acknowledge an important limitation of their study, that: “an evaluation of the effectiveness of reprocessing scopes in EVOTECH ECR versus Medivators DSD-201 could not be incorporated in conjunction with the time and motion study.” This is important to have noted, because an automated reprocessing device might be considerably more efficient to operate, but this apparent advantage is an obvious safety hazard if the device renders the processed endoscope less clean and more likely to transmit disease. It is true that, in general, comparisons of the effectiveness of different automated endoscope reprocessors requires some type of an evaluation of their comparative clinical effectiveness.”

Author Reply: We agree with the reviewer’s statement and we have referred readers to an actual practice clinical effectiveness evaluation of EVOTECH ECR conducted by Alfa et al. (Alfa MJ, Degagne P, Olson N, Fatima I. EVOTECH® endoscope cleaner and reprocessor (ECR) simulated-use and clinical-use evaluation of cleaning efficacy. BMC Infectious Diseases 2010;10:200 (doi:10.1186/1471-2334-10-200).)

Comment 6: “Table 5 of the manuscript states: “Cidex OPA in ultrasonic.” The authors are asked to clarify this statement’s meaning, understanding that the Medivators DSD-201 is not equipped with ultrasonic technology”

Author Reply: Information has been added to Table 5 to clarify that the ultrasonic device is used to clean the multiuse brushes.

Comment 7: “The authors are respectfully asked to comment briefly on whether the data, results and conclusions of their study – namely, that the Evotech, compared to the
Medivators DSD-201 reprocessing device, was more efficient and less costly to use – might apply to other marketed automated reprocessing devices. That is, the authors are asked to briefly discuss in the manuscript whether they would expect the Evotech to be “more efficient and less costly to use for the reprocessing of endoscopes” than (in addition to the Medivators DSD-201) every other automated reprocessor on the Canadian market (e.g., the STERIS Reliance EPS, or another of Medivators’ several marketed automated endoscope reprocessing models).”

**Author Reply:** Information was added to the discussion to note that it was beyond the scope of the study to determine if EVOTECH ECR would be more efficient and less costly to use than all other marketed automated reprocessing devices.

**Comment 8:** “The study uses for its calculations a technician wage of $22.20 per hour. It also states that: “All cost figures are reported in Canadian dollars.” The authors are asked to briefly apply their results to the U.S. and discuss, for example, how this rate of $22.20 per hour in Canada might compare to labor costs in the U.S., whether this manuscript’s results, cost analysis, and conclusions are unique to Canada, and whether the manuscript’s conclusions might change significantly if applied to the labor costs in the U.S.”

**Author Reply:** Information on the cost implications for the U.S. were not added to the manuscript. We felt that a discussion of the cost implications for the U.S. would be out of place in a manuscript reporting on actual practice and costs in Canada. If U.S. reviewers would like to understand the cost implication of the labour savings in the U.S., they could estimate the U.S. labour cost savings by multiplying the hours saved with EVOTECH ECR by their own institutional technician per hour labour cost.

**Comment 9:** “The authors state that “once (the endoscope was) placed in the reprocessors, the actual length of each reprocessing period was not timed because it was not practical to do so.” The authors are respectfully asked to explain further and discuss why this measurement was impractical.”

**Author Reply:** Information was added to the manuscript methods section to explain why it was impractical to time the automated reprocessing period for each reprocessing cycle.

**Comment 10:** “What immersion time did the authors use for the Cidex OPA solution to calculate the reprocessing times and efficiency associated with the Medivators DSD-201, 5 or 12 minutes, or another comparable time? Mentioning this time in the manuscript is recommended.”

**Author Reply:** As with the EVOTECH ECR cycles, further information on the automated cycle parameters (e.g., Cidex OPA immersion time and water rinse time) was added.

**Comment 11:** “The authors are therefore respectfully asked to explain in the manuscript why Table 7’s “total cost” calculations do not include the purchase price of each reprocessor (and, if relevant, why this table also does not include the approximate annual cost of labor and materials to maintain each device in working order as might be associated with, or required by, a manufacturer’s annual or quarterly preventive-maintenance policy or contract, which is independent from the costs of replacing the devices’ water filters, to ensure that the terms of their manufacturer warranties are not voided).”

**Author Reply:** We agree with the reviewer that the study did not include the reprocessor purchase price and the annual cost of maintenance contracts. We have removed reference in the manuscript to the capital costs. The primary reason for excluding these
costs is the fact that, in Canadian hospitals, the operating budgets do not cover capital costs and vice versa. The target audience for the submitted paper is hospital decision-makers interested in operating costs. A secondary reason for excluding the capital purchase price of the reprocessors was the fact that, although prices appear to be publicly available in the U.S., comparative pricing was not available for Canada.

Comment 12: “Therefore, because performing the calculations for the Medivators device using the more expensive Cidex OPA (compared to 2% glutaraldehyde) might introduce a measurement bias, the authors are respectfully requested to perform a similar set of calculations using 2% glutaraldehyde (in addition to Cidex OPA) and include these calculations (or, at least, discuss them) in the manuscript if the result of such a calculation could affect the manuscript’s conclusions, which seems likely.”

Author Reply: The reviewer’s comment that the per cycle and annual total costs with the Medivators reprocessor could be reduced with the use of glutaraldehyde is correct. Therefore, a comment regarding the potential for a reduction in cost with the use of glutaraldehyde was added as a footnote to Table 5 where the consumable supplies and their costs are displayed. However, we would like to clarify that the purpose of the study was to observe actual practice without changing any parameters or variables in the methods used at the study site to reprocess endoscopes. At no time was an attempt made to change practice in order to change the results of the study or to “compare apples to apples”. The study site exclusively used Cidex OPA as the disinfectant in the Medivators cycles and, thus, the cost of Cidex OPA was incorporated in the analysis. As noted in the footnote to Table 5, due to health risks associated with the use of other disinfectants, glutaraldehyde is not commonly used in Canada and is not used at the study site.

Comment 13: “The authors are respectfully asked to clarify whether the EvoTech (and Medivators) reprocessing device can reprocess ERCP side-viewing duodenoscopes (with an exposed wire channel), double-channel colonoscopes, enteroscopes, and ultrasound gastrovideoscopes. If the Evotech cannot reprocess at least one of these types of GI endoscopes, then the authors are asked to discuss the relevancy of this limitation vis-à-vis their manuscript and how this limitation might affect their study’s data and conclusions claiming the enhanced efficiency of the Evotech, compared to the Medivators device. This clarification raises at least two additional points that, too, might have impact on the manuscript’s conclusion that “the EvoTech ECR was more efficient and less costly to use for the reprocessing of endoscopes than the Medivators DSD-201 in this actual practice study conducted in a high-volume endoscopy unit.” Namely, the authors are similarly asked to discuss the relevancy and potential effect on their manuscript’s results and conclusions of a medical facility that, first, unavoidably uses endoscopes on patients during emergency procedures (i.e., patients were not properly prepped prior to the procedure); and, second, cannot always avoid reprocessing soiled endoscopes more than one hour after their clinical use.”

Author Reply: We agree with the reviewer’s comment that manual cleaning is required in cases of emergency procedures (i.e., patients were not properly prepped prior to the procedure) and where soiled endoscopes are not reprocessed within one hour after their clinical use. Information was available in the introduction section of the manuscript to describe this; however, we have also repeated this information in the discussion section to ensure that readers understand the impact that the manual cleaning requirement in these two scenarios would have on the overall costs. With respect to the types of scopes that can and cannot be reprocessed with EVOTECH ECR, EVOTECH ECR can reprocess most scope types including ERCP scopes, enteroscopes and videoscopes;
however, double biopsy channel scopes and ultrasound scopes must be reprocessed in another manner. A sentence was added to the discussion to state that the EVOTECH ECR cannot reprocess all scope types.

Referee 2

Comment: “I only regret that few endoscopes were reprocessed”.

Author Reply: We observed the reprocessing of all scopes in the hospital endoscopy unit over a three day period. We felt that this would provide a good representation of the usual reprocessing times. Due to the timing of breaks, the full cycle of all scopes reprocessed each day could not be observed. Nevertheless, the interquartile ranges around the median reprocessing times for each scope type indicate that the variability in reprocessing duration within a scope type was low. Similarly, despite what might be considered a small number of scopes, the difference in reprocessing time across the two reprocessor types was highly statistically significant.

Referee 3

Comment 1: “It is unclear in the methods section if the Medivator DSD-201 had an automated cleaning cycle that was routinely used in addition to the required manual cleaning. From the supplies listing in Table 5 it would appear that there was a cleaning cycle that was part of the Medivator DSD-201 process since there was detergent costs listed. The following need clarification in the manuscript:
- The cycle parameters of the EVOTECH and the Medivator AERs that were used should be clearly stated. The authors should clarify that each scope is run in a separate basin for both the EVOTECH and the Medivator units evaluated. The authors should also indicate if the cleaning cycle in the Medivator DSD-201 is optional. If the cleaning cycle in the Medivator was NOT used and only the manual cleaning was done - what would be the time impact?”

Author Reply: We agree that further information to provide clarity to manual cleaning steps versus automated cleaning and reprocessing of endoscopes in separate basins was required. We have added this information to the manuscript. We have also added further information on the cycle parameters (e.g., disinfection and water rinse times) for both EVOTECH ECR and the comparator AER.

Comment 2: “The authors need to clarify what the sequence of steps were for the cleaning process that was used. If the manual rinsing with tap water was omitted because the scope was being placed in the Medivator that would then use the cleaning cycle this should be clarified.”

Author Reply: Information was added to Table 1 to indicate that, during the manual cleaning process, the endoscopes were rinsed with tap water internally and externally.

Comment 3: “The authors should include what the time differential would be if the manual cleaning included the labour required to transfer of the scope from enzymatic to perform a thorough tap water rinse of the external surfaces and all the channels. This also needs to be taken into consideration in Table 4 as the data as presented do not include the labour required for the tap water rinse in the manual cleaning process.”

Author Reply: As per comment 2, information was added to Table 1 to indicate that a tap water rinse was included in the manual cleaning of endoscopes to be reprocessed in
in the Medivators DSD-201. It is also noted in the discussion that the study was not biased in favour of EVOTECH ECR because the study site employed an automated device to manually flush the endoscopes to be reprocessed in the AER with enzymatic solution followed by tap water. This automated process likely reduced manual cleaning time by removing the need for staff to transfer the endoscopes into different solutions. In addition, all of the operator’s time required to manually enter patient, procedure, physician and operator information into the EVOTECH was captured (while similar data was not collected for endoscopes reprocessed in the Medivators DSD-201). For these two reasons, the labour time difference between EVOTEC ECR and Medivators DSD-201 is expected to be even greater at other endoscopy clinics.

**Comment 4:** “In Table 4 and in the discussion there is no consideration given to concurrent processing of two scopes at the same time in the Medivator and Evotech units. The average daily reprocessing times given in Table 4 give the impression that the total daily time savings for reprocessing of all scopes would be 6.2 hours. However, what has not been accounted for is that most times two scopes are run concurrently in each AER so the actual saved time would be more like 3.1 hours of actual clinic time. They should be able to determine what percentage of scopes get run concurrently (i.e. two scopes run in the AER at the same time) versus the percentage of scopes that get run sequentially. This would give a more meaningful estimated of actual time savings per clinic day.”

**Author Reply:** Additional information was added to the manuscript to clarify that endoscopes could be reprocessed concurrently in up to 8 separate basins and that, with concurrent processing, the total net time saved with EVOTECH ECR could be less than 6.2 hours. Because the study was designed to look at the reprocessing times on a micro level with both types of reprocessors in use on the same day, it was not possible to determine how the different reprocessor types and differing cycle durations would impact the total length of a reprocessing day and/or the efficient use of the laboratory personnel. The purpose of calculating the difference in the total reprocessing time for each reprocessor type was to indicate the length of time that could be freed up for reprocessing additional endoscopes and/or potentially reallocating staff to other duties. It is noted in the discussion that it would be interesting to do further research to determine the net difference in laboratory time to examine efficiency further where a single reprocessor type was used on some days and the other type on other days. This type of study would permit a comparison of the true difference in time that would be required to reprocess all scopes with a given reprocessor type.

**Comment 5:** “Table 5: For the Medivator, Cidex OPA cost is listed. In addition, there is a listing for “Cidex OPA in ultrasonic” as well as “CIDEX”. It is unclear what these last two represent or where in the Medivator cycle they are used. The authors should clarify at what point in the scope reprocessing cycle these are used or whether they are used for decontamination of the Medivator itself?? Table 5: It is unclear how what the “Blue wipes” and “Blue wraps” are used for? The authors should clarify if these are used in the manual cleaning process??.”

**Author Reply:** Information was added to Table 5 to clarify the use of Cidex OPA in the Medivator and in the ultrasonic device and the function of the blue wipes and blue wraps.

**Comment 6:** “Table 4 title: Currently it states "annual" in the title, but there is not data given for annual reprocessing or labour times. The word "annual" should be omitted from the title.”
'Author Reply': The word annual was removed.
Referee 4

Comment: “My only major criticism is the study approach that is not in agreement with the clinical expectations of this Journal readers. Indeed, it seems that the Authors simply wanted to show the superiority of one machine over the other, that is an industrial competition that is of no sense for clinician readers. Therefore, the Authors need to re-write the manuscript clarifying that the primary end-point was to compare the cost of two different approaches of reprocessing, citing only marginally and no more than 2-3 times in all the manuscript which machines were used to run this comparison. Probably, the analysis could be limited to the saving in technician time without providing further details on the cost of consumables. The latter is again more an industrial competition rather than a clinical message.”

Author Reply: We have added more information to clarify that the objective of the study was to compare the cost of two different approaches of reprocessing. We have removed most of the references to the name of the comparator reprocessor and have, instead, referred to it by the more general term of “manual cleaning plus AER” to reflect the reprocessor type rather than the specific Brand and model name. We feel that the manuscript is of relevance to hospital administrators responsible for the efficient use of budgetary funds and, therefore, we believe that the technician time and cost of consumables are both very relevant for that audience.

We hope that the revised manuscript will meet with the reviewers’ approval and the standards for publication in the Journal. Please do not hesitate to email or call me if you have any further questions or comments. I can be reached at 416-453-8350 or lindy.forte@sympatico.ca.

Sincerely,

Lindy Forte, MSc