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ORIGINAL ARTICLE

Laparoscopic ventral hernia repair: outcomes in primary versus incisional hernias: no effect of defect closure

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Abstract
Purpose Supposing divergent aetiology, we found it interesting to investigate outcomes between primary (PH) versus incisional (IH) hernias. In addition, we wanted to analyse the effect of defect closure and mesh fixation techniques.
Methods 37 patients with PH and 70 with IH were enrolled in a prospective cohort-study, treated with laparoscopic ventral hernia repair (LVHR) and randomised to ± transfascial sutures. In addition, we analysed results from a retrospective study with 36 PH and 51 IH patients. Mean follow-up time was 38 months in the prospective study and 27 months in the retrospective study.
Results 35 % of PH's and 10 % of IH's were recurrences after previous suture repair. No late infections or mesh removals occurred. Recurrence rates in the prospective study were 0 vs. 4.3 % ($p = 0.55$) and the complication rates were 16 vs. 27 % ($p = 0.24$) in favour of the PH cohort. The IH group had a mesh protrusion rate of 13 vs. 5 % in the PH group ($p = 0.32$), and significantly ($p < 0.01$) larger hernias and adhesion score, longer operating time (100 vs. 79 min) and admission time (2.8 vs. 1.6 days). Closure of the hernia defect did not influence rate of seroma, pain at 2 months, protrusion or recurrence. An overall increased complication rate was seen after defect closure (OR 3.42; CI 1.25–9.33).
Conclusions With PH, in comparison to IH treated with LVHR, no differences were observed regarding recurrence, protrusion or complication rates. Defect closure (raphe), when using absorbable suture, did not benefit long-term outcomes and caused a higher overall complication rate. (ClinicalTrials.gov number: NCT00455299).

Keywords Hernia · Ventral · Primary · Incisional · Laparoscopy · Repair

Registrations and approvals This study is registered in ClinicalTrials.gov with the identifier NCT00455299 and recommended by the Norwegian ethical committee in South Norway with unique protocol ID S-06466b and the Norwegian social science data services with identification number 15731—as well as the participating parties' local science committees.

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Introduction

Until recently, most publications have failed to discern between primary abdominal wall hernias (PH) and (secondary) incisional hernias (IH), when reporting results from laparoscopic ventral hernia repair (LVHR). These entities have different aetiology and pathogenesis. Recent publications indicate that they also have different outcomes [1–3].

A retrospective study comparing open and laparoscopic mesh repair of PH found laparoscopic repair advantageous regarding surgical site infections, but reported bulging of the repair in 21.5 % of the patients and a port-site hernia rate of 2.5 % in addition to recurrence rate of 11.4 %—equal to open repair [4]. Another study reported a radiographically proven bulging rate after LVHR of 31.5 %, a seroma rate of 19.9 % and a recurrence rate of 12.4 % [5]. No randomised studies demonstrating the potential benefits of defect closure have been published.

The primary aim of the present study was to compare outcomes between PH and IH patients after LHVR. Primary endpoints were hernia recurrence and mesh protrusion and secondary endpoints included infection, seroma, overall complications and persistent pain at two months postoperatively. In addition, we wanted to assess the effect of hernia size and defect closure (raphe) on these study endpoints: perioperative events, complications and long-term outcome.

Methods

Material

Data were extracted from two separate studies comprising 225 patients. Both studies were approved and recommended by the Norwegian data inspectorate and by the Norwegian Ethical Committee. Thirty-one of the patients in Study 1 belonged to a sub-cohort of organ transplanted and immunosuppressed patients and were excluded. Results from this cohort have been published previously [6]. Thus, 194 patients from the following two studies were investigated:

Study 1 was a randomised controlled multicentre study with PH and IH including recurrences. The hernias were situated in the midline as well as laterally. These patients were enrolled for treatment by LVHR and prospective follow-up for a period of 3 years. Thirty-seven patients with PH and 70 patients with IH were included from 2007 to 2010. No patients were excluded due to surgical strategy. During the inclusion period 31 patients treated with LVHR were not included for one of three reasons: Patients living far away with difficult follow-up, patient refusing to participate in randomization and follow-up or failure to obtain consent for inclusion by the surgeon. Mean follow-up time was 38 months with 95 % completing follow-up.

Two surgical centres in Norway participated: one university hospital and one community teaching hospital with emphasis on advanced laparoscopic procedures. Twenty per cent of the patients were operated at the university hospital and 80 % at the community hospital. All patients were Caucasian and had submitted verbal and written informed consents certified by the Norwegian Ethical Committee. The study was reported to ClinicalTrials.gov prior to inclusion.

Study 2 was a retrospective study, including 51 patients with IH and 36 patients with PH. These were the first 87 patients consecutively operated with LVHR at the community hospital from October 2002 to June 2006. For quality control, a protocol with long-term follow-up was outlined. In December 2006 the patients were interviewed, and a clinical examination was performed. Patients reporting pain or bulging and patients with clinical bulging were examined by ultrasound and/or CT scan for determination of recurrence. Mean follow-up time was 27 (6–51) months. Oral and written informed consents were given before clinical control. Although we consider there is additional value from this study it is only presented in the form of tables and included in select sections of the discussion.

Surgery

All patients were operated by laparoscopic technique. For creation of pneumoperitoneum open access by mini-incision or Verres' needle was employed. Mostly three trocars were used, but in a few patients, one or two trocars were added for dissection or to accomplish secure mesh fixation. The hernia sac contents were completely reduced and the mesh-receiving abdominal wall was stripped of preperitoneal fat.

In study 1 a polyester-based mesh with collagen barrier for intraperitoneal use (Parietex Composite Mesh, Covidien, Mansfield, MA, USA) was introduced—targeted in size for a minimum of 5 cm overlap of the hernia in primary hernias or the whole previous incision in incisional hernias—and fixated to the abdominal wall. The patients were randomised to closure of the fascia defect (raphe) or not [7]. In addition, they were randomised for two different fixation techniques: Four non-absorbable corner stay-sutures and one ring of non-absorbable tackers (ProTack, Covidien) or only tack fixation without stay-sutures, but with both an outer and an inner ring of tackers ("Double Crown") [8]. Thus, four unbalanced randomisation groups were created in clusters of eight: suture-raphe, suture-non-raphe, double crown-raphe, double crown-non-raphe.

Defect closure was achieved by intracorporeal suture in a figure of eight and extrafascial knotting with absorbable Polyglactin 1 suture. Trocar sites above 5 mm were closed with absorbable suture.

In study 2 the same surgical techniques were applied, but not in a randomised fashion. Additionally, a variety of meshes were used: In 72 patients (83 %) Parietex Composite Mesh (Sofradim), in five patients Composix and Composix E/X meshes (Bard), in four patients Dualmesh (Gore) and in two patients Proceed meshes (Ethicon).

Collection of data

Study 1: The patients were invited to clinical control at their respective hospitals 2 months and 3 years after the operation. Adverse events observed by patient and clinician were recorded. If recurrence or protrusion of mesh through hernia defect was detected or suspected, patients were examined by ultrasonography, including the Valsalva manoeuvre. In some patients, a CT scan was supplementary. The recorded perioperative information included heart disease, type and topography of hernia, previous hernia treatment, access method for laparoscopy, number and size of used trocars, pain level (VAS score), pain duration, time to normal activity and duration of sick-leave, in addition to the variables presented in Tables 1, 2 and 3. Adhesions were defined according to Zuhlke [9] and physical score according to American Association of Anaesthesiologists physical score (ASA).

Mesh protrusion was defined as a bulge at the previous hernia defect, the defect still completely covered and abdominal content retained by the implanted mesh. Any perceivable bulging not classified as recurrence after clinical and ultrasonographic evaluation was recorded as protrusion in this study. Protrusion was classified as small (< 2.5 cm), medium (2.5–5.0 cm) or large (> 5.0 cm) in prominence above the abdominal wall during Valsalva manoeuvre in supine position. In addition, complications as enterotomies, mesh infections, wound infections, reoperations, seroma formations and long-term pain were recorded.

Study 2: A similar control as in study 1 was implemented in December 2006 and the same data were assembled by interview and clinical examination, except for grading of protrusion, which was simply recorded dichotomously. Data on time to normal activity, sick leave and adhesion score from the perioperative registry was not recorded.

Data analysis

The following study factors were categorized into ordinal variables with three categories: hernia area ellipsoid (≤ 20 cm^2, > 20 and $100 \leq$ cm^2, and > 100 cm^2) and a calculated overlap coefficient (≥ 1, < 1 and ≥ 0.8, and < 0.8). The treatment group was dichotomous (PH vs. IH patients) as was defect closure. Four possible confounding variables were included for adjustment: Body Mass Index (BMI) was divided into three categories ($\leq$ 25 kg/m2, $>$ 25 and $<$ 30 kg/m2, and $\geq$ 30 kg/m2) and age in years ($<$ 50, $\geq$ 50 and $<$ 60, and $\geq$ 60), while sex and chronic obstructive pulmonary disease (COPD) were dichotomous.

The one-dimensional overlap coefficient was defined as the least difference between mesh size and hernia size in two directions, divided by the double of the targeted mesh overlap of 5 cm in any direction [10]. In multiple hernia, the hernia length was determined as the distance between the most extreme hernia edges, and the width as the widest of the multiple hernias. For comparison with other studies,

Table 1 Laparoscopic ventral hernia repair: demographic data and patient/disease characteristics, incisional and primary hernia cohorts, prospective and retrospective studies

	Prospective study (study 1)		Retrospective study (study 2)	
	Incisional hernia	Primary hernia	Incisional hernia	Primary hernia
Age, years, mean (range)[a]	**57 (32–81)**	**57 (33–82)**	61 (31-84)*	51 (26–84)*
ASA[b], 0–E, mean (range)[a]	**1.8 (1–3)**	**1.7 (1–3)**	1.9 (1–3)	1.7 (1–3)
Body Mass Index, kg/m^2, mean (range)[a]	**30 (20–50)**	**30 (20–50)**	31 (19–54)	30 (20-48)
COPD[c], n (%)[d]	**9 (13)**	**2 (5)**	5 (10)	3 (8)
Female/male, n/n[d]	**55/15***	**11/26***	37/14*	17/19*
Recurrent hernia, n (%)[d]	**7 (10)***	**13 (35)***	5 (10)*	12 (33)*
Recurrent hernia, sex distribution, female/male, n/n[d]	**7/0**	**7/6***	3/2	7/5

Randomised study is in bold

* Statistically significant ($p < 0.05$)

[a] Independent samples t test

[b] American association of anaesthesiologists physical score

[c] Chronic obstructive pulmonary disease

[d] Fisher exact test

Table 2 Laparoscopic ventral hernia repair: perioperative data and events, incisional and primary hernia cohorts, prospective and restrospective studies

	Prospective study (study 1)		Retrospective study (study 2)	
	Incisional hernia	Primary hernia	Incisional hernia	Primary hernia
Hernia Area Quadratic, cm^2, Median (range)[a]	**24 (1–405)***	**9 (1–112)***	20 (4–405)*	6 (1–200)*
Hernia Area Ellipsoid, cm^2, Median (range)[a]	**19 (1–318)***	**7 (1–88)***	16 (3–318)*	5 (1–157)*
Overlap Coefficient[b], Median (range)[a]	**1.0 (0.5–1.8)**	**1.0 (0.7–1.7)**	1.0 (0.5–1.8)*	0.8 (0.7–1.5)*
Defect closure, *n* (%)	**36 (51)**	**21 (58)**	10 (20)	7 (19)
Double Crown mesh fixation[c], *n* (%)	**37 (53)**	**20 (54)**	32 (63)	21 (58)

Randomised study is in bold

* Statistically significant ($p < 0.05$)

[a] Mann–Whitney *U* Test (non-binomial distribution)

[b] Coefficient of ideal overlap, 1.0 equals 5 cm overlap [6, 10]

[c] Mesh fixation according to Morales–Conde [8]

Table 3 Laparoscopic ventral hernia repair: outcome, incisional and primary hernia cohorts, prospective and retrospective studies

	Prospective study(study 1)		Retrospective study (study 2)	
	Incisional hernia *n* (%)	Primary hernia *n* (%)	Incisional hernia *n* (%)	Primary hernia *n* (%)
Recurrence of hernia	**3 (4.3)**	**0**	4 (7.8)	1 (2.8)
Protrusion of mesh	**9 (12.8)**	**2 (5.4)**	1	1
Pain at 2 months	**18 (25.7)**	**11 (29.7)**	10 (19.6)	4 (11.1)
Follow-up, months, mean (range)	**38 (12–73)**	**39 (25–54)**	27 (6–50)	28 (7–49)

Randomised study is in bold

hernia size in quadratic area (multiplication of hernia length and hernia width,) was calculated in addition to the more geometrically sound ellipsoid area calculation (area calculation by ellipsoid formula: $\pi/4$* A * B, where A and B are the two diagonals), and the area for in-growth derived by subtracting ellipsoid area hernia size from mesh area.

The studied endpoints were all dichotomous variables. The associations between treatment group (PH vs. IH) and hematoma and re-operation, respectively, were analysed bivariately using Fisher's exact test, Independent samples *t* test and Mann–Whitney *U* Test where applicable (two-tailed). Randomization groups were analysed in contingency tables with Fisher's exact test and Freeman–Halton extension. The other endpoints were analysed in four multiple logistic regression models. The adjusted odds of recurrence and protrusion, respectively, were estimated for randomization to defect closure, hernia area ellipsoid, overlap coefficient and treatment group, adjusted for BMI, age, chronic obstructive pulmonary disease (COPD) and sex. The same study factors were included in the analysis with seroma as the endpoint, but without adjustment for additional factors. The PH: IH odds ratio of infection was adjusted for BMI.

The significance level was set at five percent in all tests. Odds ratios (OR) with 95 % confidence intervals (CI) are reported for all study factors included in each regression model, and the p values from the Fisher's exact tests.

Results

Baseline and perioperative characteristics

As shown in Table 1 the studied cohorts were similar with regard to age, physical health score, BMI and COPD. However, females were predominant in the IH group, and males in the PH group ($p < 0.001$). Recurrent hernias were more prevalent among the PH patients (35 vs. 10 %, $p < 0.01$) and with females in majority ($p = 0.03$). Previous hernia repair in the prospective IH group was performed with suture only repair in six of seven cases and on-lay mesh in one case. In the prospective PH group, eleven of thirteen previous repairs were by suture only, whereas one was an on-lay repair and one was a LVHR.

Two Spigelian, 15 epigastric (3 recurrent) and 20 umbilical (10 recurrent) hernias constituted the prospective PH group. In the prospective IH group 13 hernias had

osseous proximity: two sub-xiphoid, three suprapubic, six subcostal and two crista-near hernias. The remaining 57 IH's were situated in the midline. In addition, one parastomal (modified Sugarbaker), one epigastric, one inguinal and two Spigelian hernias were repaired in conjunction to IH repair. Hernia size was larger in the IH group ($p < 0.01$), as was operating time (100 vs. 79 min.; $p < 0.01$) and admission time (2.8 vs. 1.6 days; $p < 0.01$). Defect closure did not influence operating time significantly. Zuhlke adhesion score was higher in the IH group ($p < 0.01$). A satisfactory mesh overlap was achieved in both cohorts (Table 2). One patient became pregnant during the follow-up period and completed her pregnancy without adversities.

Complications

The IH or PH groups were not associated with any of the endpoints (Tables 3, 4). The total complication rates were 27 vs. 16 % ($p = 0.24$). Seroma formation was not correlated to infection, recurrence or protrusion. The difference in enterotomy rate (1.4 vs. 0 %) did not reach statistical significance. The two reoperations for bleeding and intestinal perforation were in the IH group. The enteric lesion resulted in mesh removal and recurrence of incisional hernia. Otherwise no mesh removal was necessary.

One quarter of the patients had pain at two-month control with no difference between cohorts (OR 0.59; CI 0.18–1.94). There were also no differences in the two-month pain rates between patients with +/− defect closure (OR 0.54; CI 0.21–1.37).

None of the studied factors (Table 4) were associated with infection, but higher BMI (adjustment factor) was associated with overall complications (OR 1.87; CI 1.14–3.05). However, in adjusted analysis the proportion of patients with overall complications increased with hernia defect closure (OR 3.42; CI 1.25–9.33), but was not associated to PH or IH. A binary subanalysis revealed that overall complications related to defect closure was primarily a feature of the PH group ($p < 0.01$), and not significant in the IH group ($p = 0.43$). Mesh fixation method was not associated with complications or primary endpoints in bivariate analysis and was therefore removed from adjusted analysis.

Recurrence

The recurrence rate in the IH cohort was 4.3 vs. 0 %. The observed difference was not significant in bivariate analyses ($p = 0.55$, Table 3) and since no recurrence occurred in the prospective PH cohort adjusted analysis was not applicable.

Hernia recurrence occurred in all cases after initial repairs, i.e. not recurrent hernia repairs. COPD was removed from the adjusted analysis model, since none of the 19 patients with this condition acquired a recurrence. There were no trocar site hernias in the study period, however trocar hernias have occurred later in two cases, in one patient from each cohort.

Protrusion

Mesh protrusion was found in 13 % in the IH group and 5 % in the PH group ($p = 0.32$). The adjusted OR was 3.51 (95 % CI 0.47–26.18). More protrusions were found among males in the IH group ($p = 0.02$), but males also had larger hernias ($p = 0.03$). All cases of protrusions were asymptomatic. Defect closure had no significant effect on recurrence, protrusion or seroma formation. Full closure was achieved in all allocated patients. For patients with large hernia size (ellipsoid hernia area > 20 cm^2) the OR for protrusion was 2.30 (CI 0.73–7.19). Large overlap

Table 4 Laparoscopic incisional hernia repair on incisional and primary hernia cohorts with randomisation to defect closure: The adjusted odds ratios (with 95 % Wald confidence intervals) for recurrence, protrusion, seroma and infection for study factors in the multivariate models

Prospective study (study 1)	Recurrence[a]	Protrusion[b]	Seroma	Infection	Pain at 2 months[b]	Complications[b]
Incisional hernia Reference category: primary hernia	Not applicable (NA)	3.51 (0.47–26.18)	1.48 (0.35–6.28)	0.92 (0.18–4.63)	0.59 (0.18–1.94)	1.28 (0.38-4.34)
Defect closure Reference category: no defect closure	NA	0.66 (0.15–2.88)	3.34 (0.84–13.35)	2.74 (0.52–14.52)	0.54 (0.21–1.37)	3.42 (1.25-9.33)
Hernia size (ellipsoid) Reference category: ≤ 20 cm^2	NA	2.30 (0.73–7.19)	1.35 (0.55–3.32)	1.30 (0.41–4.10)	0.64 (0.26–1.59)	0.98 (0.43–2.23)
Overlap coefficient[c] Reference category: ≥ 1.0	NA	0.59 (0.16–2.13)	0.66 (0.22–1.94)	1.35 (0.48–3.84)	1.13 (0.56–2.28)	1.27 (0.62–2.61)

[a] Adjusted for age, body mass index and sex

[b] Adjusted for age, body mass index, chronic obstructive pulmonary disease and sex

[c] Coefficient of ideal overlap [6, 10]

(overlap coefficient $\geq$ 1.0 i.e., overlap $\geq$ 5 cm) seemed to counter this risk (OR 0.59; CI 0.16–2.13).

Discussion

Baseline characteristics

In 10 % of the IH and in 35 % of the PH patients participating in this study, the hernias were recurrent and in almost all these patients the previous repair had been performed by suture only. A similar distribution is seen in study 2. This may reflect that the recurrence rate by suture-only repair is high and equally insufficient in IH and PH patients [11–13]. Many cases of IH are considered to be caused by infectious problems or insufficient closure technique [14], whereas PH may be associated with inherent abdominal wall weakness [15–20]. Thus, it seems at least as important to treat PH patients by a reinforcing mesh, as many of these may suffer from congenital polymorphisms/defects in collagen or other structural proteins. However, a fraction of the IH patients must also be expected to have inherent/pre-existing weaknesses with regard to structural protein and scar/incisional repair. In this study we have allocated recurrent PH (rPH) to the PH group. This allocation choice should be challenged, as a recurrent open repair of a PH would share many characteristics of an IH, regarding both perioperative challenges and long-term outcomes. We have therefore performed uni- and bivariate post hoc analyses allocating rPH to the IH group and with eliminating recurrent hernia from the dataset. These analyses did not alter the study results compared to the a priori analysis plan.

During recent years, guidelines advocate mesh repair for PH, even with defects less than 2 cm in diameter, especially in obese patients and preferably by LVHR [21]. Taking into account that an open suture-only repair is a low-risk/low-cost procedure [22], with a low-seroma and infection rate [23], the technique may still be considered acceptable with small hernias and given thorough information about recurrence risks. The sex distribution observed in this study, with a higher rate of female IH's and of male PH's, is both sustained [11] and contradicted [12] in other studies.

Complications

No significant differences in the overall complication risk between the PH and IH groups were found. However, the adjusted analysis showed a tendency towards increased risk for seroma formation in the IH group, in patients with defect closure and with increasing hernia size. Furthermore, a tendency towards lower odds for pain at 2 months was found in the IH cohort, and with defect closure.

Seroma constitutes half of the complications in both cohorts. All seromas regressed spontaneously and seromas were not correlated to infection or protrusion in this study. Thus, seroma formation seems to be a minor complication with LVHR, as opposed to being a major problem with the open approach. In our view, avoiding the incision above the mesh makes an important difference.

Recent retrospective studies have indicated improved results by defect closure on seroma formation, eventration and recurrence [24–26]. In contrast we found a significantly higher overall complication rate with defect closure using absorbable suture, particularly pronounced in the PH group—and with no long-term benefits in either cohort. This may suggest that the previously reported efficacy of defect closure might be small and possibly exaggerated. The whole concept of defect closure is actually non-coherent with the old surgical principle of "avoiding tension", which is basically sound both from a mechanistic and a microcirculatory point of view. These data and basic considerations may suggest that defect closure may not be appropriate when dealing with small defects, where muscle adaption does not have functional effect and the tension by closure is better avoided. Otherwise, non-synthetic cover should probably be obtained by layer separation/lateral release techniques.

The uneven sex distribution between cohorts, as the majority of IH were in females and the majority of PH were in males, has not been described in previous studies. The sex distribution is adjusted for in the multiple regression analyses.

Recurrence

Though not significantly different, the proportion of hernia recurrences after LVHR was lower in the PH group, indicating that reinforcement/augmentation with mesh is beneficial in both PH and IH patients. PH's were significantly smaller than IH's, a fact that contributes to improved outcome, as larger hernias give rise to more tension on the mesh [27]. Another factor which may add to a higher recurrence rate among IH patients may be hernia locations away from the midline, with defects adjacent to the costal margin or iliac crest [28, 29]. However, in our material, none of the hernias with osseous proximity recurred. Comparing with previous reports on PH suture-only repair, we believe that our low LVHR recurrence rate does support the use of synthetic mesh, even with small PH's. However, if the follow-up period had been further extended above 3 years, we would expect a larger rate than observed. There was a slightly higher recurrence rate in the retrospective

study 2, even with a shorter follow-up. We believe the learning curve is responsible for this difference in outcome.

Protrusion

The risk of protrusion in this study was moderate and increased with hernia size. The study does support the concept of a potential benefit by increased mesh/fascial overlap, particularly in larger hernias. Defect closure did not affect the risk of protrusion, which was unexpected as protrusion in lasting closure is illogical [24]. Using absorbable suture for defect closure may be inappropriate, and in this study the number of raphe-sutures inadequate or the suture technique wanting. PH patients have supposedly alternate/impaired fibrous repair [16] in common with immunosuppressed patients, but for different reasons. In a previous study we have reported increased protrusion rate in immunosuppressed patients, but the hernia size and topography diverge considerably from PH patients [6]. We report on permanent mesh fixation devices in combination with defect closure by absorbable suture. Lately, this concept has been reversed to the opposite—namely absorbable mesh fixation materials and permanent suture for defect closure, which has been introduced without scientific evidence. Future studies will decide if this model returns different outcomes.

Conclusions

In spite of differences in aetiology, hernia size and hernia topography, LVHR in PH and IH produce satisfactory—and almost comparable outcomes—suggesting LVHR with synthetic mesh to be safe and effective for both patient groups.

In this study defect closure with absorbable suture was associated with a higher overall complication risk and with no long-term benefits.

We recommend that LVHR studies segregate analysis of outcomes to aetiology (PH and rPH vs. IH and rIH)—in addition to topography.

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Conflict of interest JL declares non-financial support (fax machine) from Covidien, Mansfield, MA, USA but otherwise no conflict of interest. AV declares no conflict of interest. ET declares no conflict of interest. OØ declares no conflict of interest. OR declares no conflict of interest.

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