In-hospital cost comparison between percutaneous pulmonary valve implantation and surgery

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Abstract

OBJECTIVES: Today, both surgical and percutaneous techniques are available for pulmonary valve implantation in patients with right ventricle outflow tract obstruction or insufficiency. In this controlled, non-randomized study the hospital costs per patient of the two treatment options were identified and compared.

METHODS: During the period of June 2011 until October 2014 cost data in 20 patients treated with the percutaneous technique and 14 patients treated with open surgery were consecutively included. Two methods for cost analysis were used, a retrospective average cost estimate (overhead costs) and a direct prospective detailed cost acquisition related to each individual patient (patient-specific costs).

RESULTS: The equipment cost, particularly the stents and valve itself was by far the main cost-driving factor in the percutaneous pulmonary valve group, representing 96% of the direct costs, whereas in the open surgery group the main costs derived from the postoperative care and particularly the stay in the intensive care department. The device-related cost in this group represented 13.5% of the direct costs. Length-of-stay-related costs in the percutaneous group were mean $3885 (1618) and mean $17 848 (5060) in the open surgery group. The difference in postoperative stay between the groups was statistically significant ($P \leq 0.001$).

CONCLUSIONS: Given the high postoperative cost in open surgery, the percutaneous procedure could be cost saving even with a device cost of more than five times the cost of the surgical device.

Keywords: Congenital pulmonary heart disease • Innovative techniques • Cost analysis • In-hospital costs

INTRODUCTION

Percutaneous pulmonary valve implantation is an alternative to open surgery in selected patients with pulmonary valve dysfunction [1]. The method involves overstenting the degenerated pulmonary valve with either a bovine jugular vein or a bovine pericardial valve [2, 3]. In Norway 62 patients have been treated so far, all of them in our hospital. Short- and midterm follow-ups have shown improved and sustained haemodynamics and an increase in exercise capacity, particularly in patients with predominant pulmonary stenosis [2, 4, 5]. Patients have reported positive experiences of the short rehabilitation time and the ability to normalize and taking part in their social life almost immediately after treatment [6]. However, there has been little detailed information on the impact of the percutaneous technique on the in-hospital costs. Thus, the purpose of this study was to identify the main cost-driving factors associated with the two techniques.

MATERIALS AND METHODS

Patients

All patients treated with pulmonary valve replacement percutaneously or surgically were recruited during a 3-year period and defined as a standard revision with no other intraoperative procedures. The inclusion was not randomized, as the percutaneous technique could not be applied in all patients, due to anatomical restrictions. The inclusion criteria were independent of procedure technique, based on international principles of treatment within

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this medical field [7] and a consensus set by the local team responsible for the patients. The study was conducted at Oslo University Hospital, the only cardiac centre in Norway offering advanced surgical and interventional treatment to patients with congenital heart defects.

Treatment procedures

The choice of valve was based on what was deemed best for the individual patient. Thus, in both groups various valves were used. For percutaneous implantation the advantage of prestenting was acknowledged during the study period to minimize the risk of stent fractures [8–10]. Prestenting was therefore not an option in the first six patients. The interventional procedures were performed in an angiography room with a team of cardiologists, anaesthesiologists and specialist nurses. All procedures were performed in general anaesthesia. The induction was done with benzodiazepines and maintained with gas and fentanyl.

The costs for prestenting were defined as a part of the percutaneous pulmonary valve implantation procedure, even in the cases where the stents were implanted 1–3 months before percutaneous pulmonary valve implantation.

In the open surgery group, all surgical procedures were carried out in an operation theatre with a team of cardiac surgeons, cardiologists, anaesthesiologists, specialist nurses and a perfusionist. All surgeries were performed on standard extracorporeal circulation. Transoesophageal echocardiography was performed in most of the surgical patients. The anaesthesia was the same for both procedures.

Setting and location

In order to monitor the costs in detail the total admission time was divided into three phases: the pre-, per- and postoperative phase. In the patients admitted for pulmonary valve replacement by open surgery, the preoperative phase of the study was defined from the admission day before surgery until transferal to the operation theatre. The preoperative phase included laboratory tests, radiological imaging, echocardiography, information from the physiotherapist and a clinical evaluation by a senior surgeon in all surgical patients. The per-operative phase was defined as the time from admission to the operation theatre until transferal to postoperative care. The postoperative phase was defined as the duration at the postoperative care unit and at the general ward. In patients referred to a local hospital before discharge to home, the time spent at the general ward was defined as the time at our hospital in addition to the time at a local hospital. The first night at the general ward all patients spent in a 'step-down room' before they were placed in a two- or four-bed room.

In the patients treated with the percutaneous technique, the preoperative phase was defined from the admission day before the intervention until transferal to the catheterization suite. They were admitted to a ward either at the adult cardiology department or at the pediatric cardiology department where laboratory tests, radiological imaging, echocardiography and a clinical evaluation by a senior cardiologist were performed. The per-operative phase was defined from admission to the catheterization suite to transferal to postoperative care.

The postoperative phase was defined as the length of stay (LOS) from the arrival at the postoperative care unit until discharge from a hospital setting. This included a stay at the paediatric or adult cardiac ward at our hospital, as well as an eventual stay at a local hospital.

Cost analysis

In both treatment groups, two different methods were used for cost analysis. One method was based on data for the individual patient (direct costs) and one was based on the overhead costs (indirect costs), with the overhead costs ultimately also allocated to the individual patient [11, 12]. By the overhead cost method, costs were based on the average estimated cost of each hour at different wards at Oslo University Hospital, Rikshospitalet. These estimates were produced by the hospital account department and comprised costs as an estimated price for each examination (echocardiography, catheter laboratory procedure, radiologic imaging, surgical procedure, etc.) based on purchase cost divided by the number of procedures performed. These costs were allocated to clinical departments and further to the specific patients by predefined allocation keys [11, 13].

The direct cost method was based on direct registration of selected costs for each patient in both groups with the basic principle to relate as much as possible of the resources used as direct costs to the individual patient [12]. The following categories were used to describe the direct resource use in both types of treatment techniques; diagnostic- and laboratory tests, medication, disposables, blood products, echocardiography, radiological imaging, procedure costs and physiotherapy. Patient-specific costs and overhead costs are reported separately for each patient group. Cost associated with the stay in a local hospital was calculated by multiplying the daily Oslo University Hospital general ward costs by the number of days they stayed at the local hospital.

All interventions were evaluated as if operating under steady-state conditions based on the budget of 2013, whereas prices of disposables (direct costs) were obtained from the university hospital procurement system using negotiated prices for 2014. Prices were consequently converted from Norwegian crowns (NOK) to US dollars (US$) with the mean exchange rate for 2014 of 1 USD ($) = 6.3 NOK. All patient costs were covered by the Norwegian public insurance system [14].

Data analysis

Due to small sample sizes of the study, data were not normally distributed, thus a bootstrapping analysis was made for both data sets to allow comparison of arithmetic means concerning analysing the costs and LOS hours without making assumptions about the data distribution [15]. A P-value <0.05 was considered as statistically significant. Mean and standard deviation or median and range were presented for normally and non-normally distributed data, respectively. Number and percentage were given for categorical data. Continuous data were examined for significant departure from normality by using histogram and Kolmogorov–Smirnov's test. Scatter plot was used to investigate whether the relationship between two continuous variables was linear (Fig. 1).

Relationship and its strength between total LOS (hours) and age (years), total LOS and weight (kilograms) or total LOS and numbers of preoperations were assessed by non-parametric correlation analysis because of non-linear relationship, non-normally distributed data and small sample sizes. Bootstrapped 95% confidence
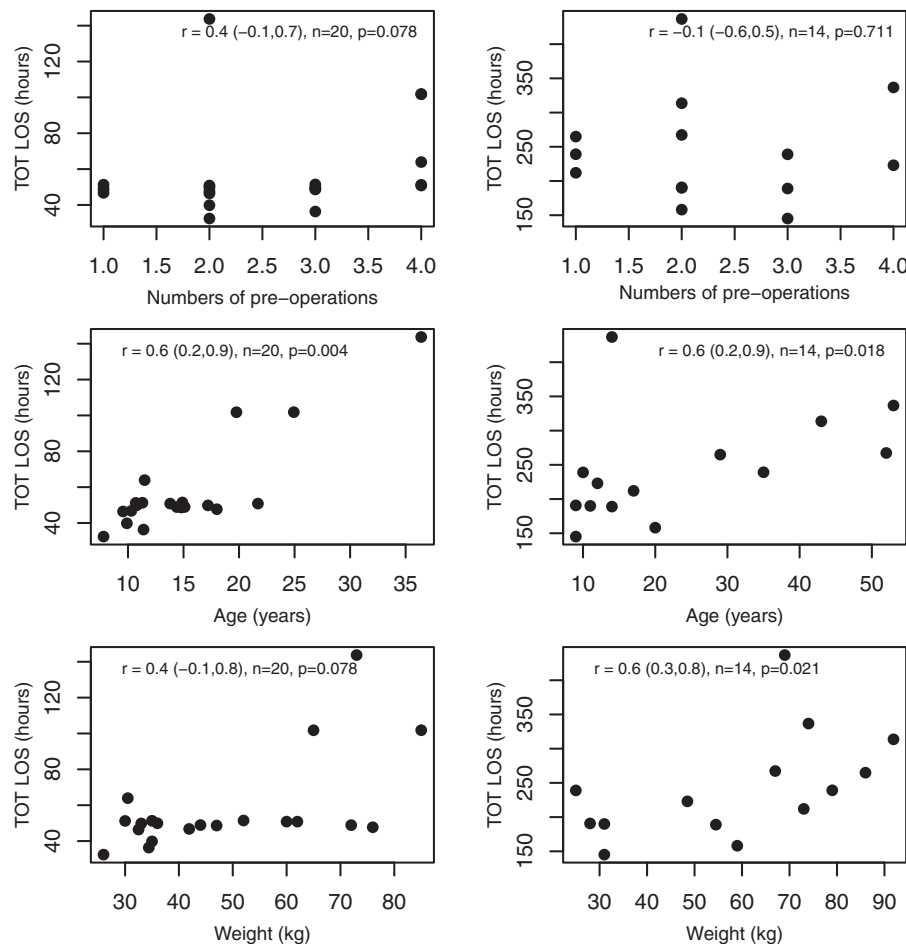
Figure 1: Scatterplots showing the relationship between total LOS and numbers of preoperations, total LOS (h) and age (years) and total LOS and weight (kg) or in the percutaneous pulmonary valve replacement group and the open surgery group.

interval (95% CI) for Spearman's correlation coefficient was based on 1000 replications and biased corrected and accelerated.

Analyses were performed in IBM Statistical Package for the Social Sciences 23 23.0.0.2 and the figures were created with R for Windows. The bootstrapping analyses were conducted in Microsoft Excel 2013.

RESULTS

Thirty-four patients were included in the study, 22 males and 12 females, aged 14 (8–36) years in the percutaneous group and 23 (9–53) years in the open surgery group (Table 1). In the 20 patients receiving percutaneous valve implantation, two of the patients were prestented 1 and 3 months before valve implantation, while nine patients were prestented during the implantation procedure. Median 1 (1–3) stents were used in these patients. Sixteen patients received a Medtronic Melody (Medtronic Inc., Minneapolis, MN, USA) valve and four patients an Edwards SAPIEN (Edwards Lifesciences, Irvine, CA, USA) valve. Of the 14 patients undergoing open surgery, 11 patients received a Carpentier-Edwards Perimount Magna (Edwards Lifesciences, Irvine, CA, USA) valve, two a Contegra bovine jugular valved conduit (Medtronic, Inc.), and one patient received a pulmonary homograft.

In the patients receiving percutaneous pulmonary valve implantation, the total length of hospital stay (LOS) was 58 (27) h and 243 (78) h in the patients treated by open surgery, thus total

LOS cost was $3885 (1618) for the percutaneous pulmonary valve group and $17 848 (5060) for the open surgery patients.

The LOS cost (overhead costs) in the percutaneous pulmonary valve implantation group was $1337 (1239) for the prephase, $238 (57) for the per-operative phase and $2309 (1433) for postoperative phase (Table 2). Cost drivers (direct costs) in the preoperative phase of the percutaneous pulmonary valve implantation group were diagnostic tests as echocardiography and X-ray expenses at the costs of $562 (257). In the open surgery patients, the LOS in-hospital cost was $1329 (952) for the preoperative phase, $247 (68) for the per-operative phase and $16 273 (5034) for postoperative phase.

Cost drivers in the per-operative phase for the percutaneous pulmonary valve implantation group were related to the device cost and represented a cost (present + valve) of $30 629 (3712). Disposable items (monitoring equipment, introducer catheters and balloons) and drugs (anaesthetics, medication, fluids) represented a minor cost for these patients $1121 (566).

Cost drivers in the per-operative phase for the open surgery group were oesophagus echocardiography representing $104 (80) and the cost of the valve conduit $3814 (655), disposables (equipment needed to perform the open surgery, heart- and lung equipment, monitoring equipment) at the cost of $2267 (195), drugs and blood products representing $1985 (2146) (Table 3).

In the percutaneous pulmonary valve group, the patients stayed 3.3 (3.6) h at the postoperative unit at a cost of $876 (1087) and 26.8 h at the general ward at a cost of $1432 (972).

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Table 1: Patient characteristics

Groups	Percutaneous pulmonary valve replacement (*n* = 20)	Open heart surgery pulmonary valve replacement (*n* = 14)	*P*-value
Female gender, *n* (%)	7 (35.0)	5 (35.7)	1.00
Age (years), median (range)	14. (8–36)	23 (9–53)	0.323
Weight (kg), median (range)	43.0 (26–85)	63.0 (25–92)	0.274
Number of previous surgeries, median (range)	2.5 (1–4)	2.0 (1–4)	0.416

Table 2: Total hospital length of stay, cost per phase based on overhead costs for percutaneous valve replacement and open surgery

| | Groups | | | | *P*-value | |
| | PPVI (*n*=20) | | Open surgery (*n*=14) | | | |
	LOS (h)	Costs	LOS (h)	Costs	LOS	Costs
Phases						
Preoperative phase						
Mean (SD)	25 (23)	1337 (1239)	32 (23)	1329 (952)	0.37	0.98
Median (range)	23 (4–117)	1215 (187–6247)	24 (15–99)	1007 (639–4075)		
Per-operative phase						
Mean (SD)	3 (1)	238 (57)	3 (1)	247 (68)	0.39	0.70
Median (range)	3 (2–5)	239 (154–428)	3 (2–5)	232 (160–410)		
Postoperative phase						
Mean (SD)	30 (19)	2309 (1433)	208 (65)	16 273 (5034)	<0.001	<0.001
Median (range)	24 (20–91)	1799 (1406–6604)	204 (119–361)	13 920 (9256–25 913)		
Total LOS						
Mean (SD)	58 (27)	3885 (1618)	243 (78)	17 848 (5060)	<0.001	<0.001
Median (range)	50 (32–144)	3223 (2244–8161)	231 (145–437)	16 347 (10 593–27 113)		

All costs are in USD ($) (2013).

Table 3: Direct costs for percutaneous valve replacement and open surgery

| | Groups | | | | *P*-value |
| Item | PPVI (*n*=20) | | Open surgery (*n*=14) | | |
	Mean (SD)	Median (range)	Mean (SD)	Median (range)	
Disposables	1121 (566)	1044 (268–1940)	2267 (195)	2421 (250–2429)	<0.001
Device/valve- conduit replacement	30 629 (3712)	32 420 (23 750–35 229)	3814 (655)	3601 (3226–5736)	<0.001
Diagnostic tests	562 (257)	53 (231–1421)	2042 (522)	1854 (1365–2940)	<0.001
Drugs	8 (17)	78 (70–141)	1196 (293)	1215 (836–1878)	<0.001
Physiotherapy	0 (0)	0 (0)	137 (48)	135 (53–219)	
Laboratory tests	33 (8)	31 (20–56)	107 (23)	107 (60–154)	<0.001
Blood products	0 (0)	0 (0)	789 (1942)	0 (0–7222)	

All costs are in USD ($) (2013).

In the open surgery group, the patients stayed 33 (22) h in the intensive care unit at a cost of $8836 (5679). Diagnostic tests represented 10% of the costs in the postoperative phase. After discharge from the postoperative unit these patients stayed 68 h (79) in a local hospital at a cost of $2834 (3261) representing 16% of cost for in the postoperative phase for this group (Fig. 2).

The Spearman rank correlation analysis demonstrated a coefficient of 0.614 (*P*= 0.004) between age and LOS, whereas in the open surgery group the coefficient was 0.621 (*P* = 0.02) demonstrating a significant correlation between LOS and the patient's age in both groups.

DISCUSSION

The overhead cost method (indirect costs) developed at our hospital was based on a department-dependent fixed price for staying in a hospital ward during pre-, per- and postoperative phase
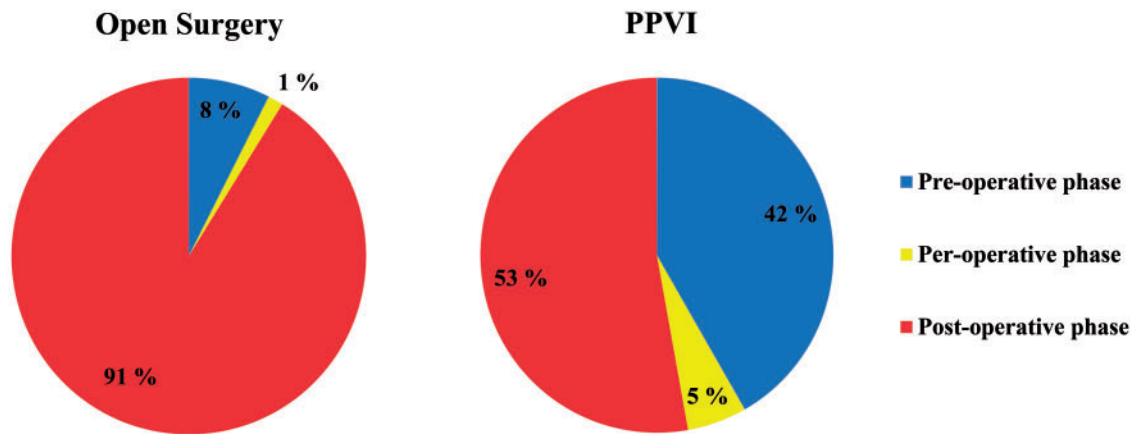
Figure 2: Overhead costs shown in percentages in the different in-hospital phases in the percutaneous pulmonary valve replacement group and the open surgery group. All costs are in USD ($).
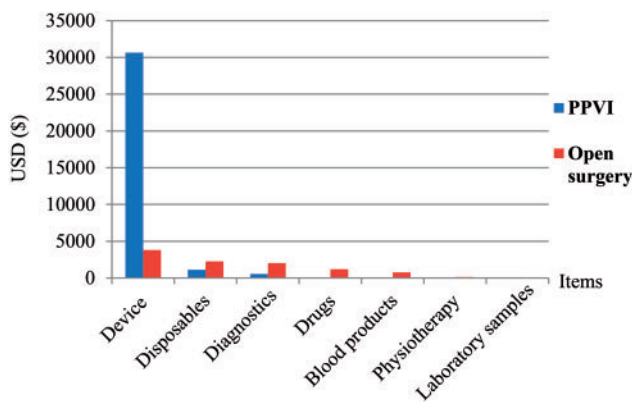
Figure 3: Direct costs in the percutaneous pulmonary valve replacement group and in the open surgery group. All costs are in USD ($).

after open surgery and a cardiac percutaneous intervention. As this method did not individualize the actual cost of the percutaneous valve and associated stents, the cost estimation by this method showed a difference in costs between the groups favouring the percutaneous technique. The major cause for this favourable outcome was the difference in LOS postoperatively. The overhead cost method was based on an average total cost for staying in a ward or intensive care unit calculated on the average of costs including diagnostics and treatment for all cardiac patients receiving surgery or percutaneous intervention. This method works well for monitoring costs of procedures that are well established and a well-known pathway.

The direct cost method (patient-specific cost) based on prospective detailed cost acquisition however, demonstrated a difference in costs favouring open surgery. The main reason for this was the price of the percutaneous valve (+equipment) representing 96% of total direct costs in this group. The direct cost method revealed reduced costs related to disposables, laboratory tests, diagnostic tests, drugs, physiotherapy and blood products for the percutaneous intervention group compared with open surgery, leaving the device cost as the singular cost-driving factor. The direct cost method revealed detailed information that was not exposed in the traditional overhead cost method. Thus the study showed that although the overhead cost method is well suited

for monitoring established methods where the average cost will represent a more or less true picture of the costs, a direct cost method is necessary to identify the main cost drivers related to the new method when new methods and technologies are introduced [16] (Fig. 3).

The study further demonstrated that when compared with open surgery, percutaneous pulmonary valve implantation in Norway could be cost saving for hospitals even with a percutaneous device cost of more than five times the cost of the surgical device. As percutaneous techniques become more frequent and more companies enter the market a reduction in the device cost may be expected and thus give a more favourable in-hospital cost outcome [17, 18].

We defined prestenting as part of the routine percutaneous valve procedure when estimating costs, even if it was not needed in all patients. Patients with less rigid outflow tracts became candidates for the percutaneous technique, even outflow tracts with predominantly native tissue were prestented and transformed to become a rigid and safe landing zone for a percutaneous valve. Thus, the inclusion criteria for percutaneous valve replacement were slightly changed during the study.

In this study, the control group and the percutaneous valve group were not identical with respect to anatomical and pathological conditions as all patients where percutaneous valve implantation was possible received such treatment, whereas the control group comprised only patients where for various reasons percutaneous treatment was not possible. However, we chose not to perform a randomized trial as that would leave too few patients in each group. Even so, we believe that the present design gives a fairly accurate picture of the cost challenges of the percutaneous technique.

In this article, we did not address complications in each group as outcome variables for cost estimation.

Instead, LOS was used as basis. LOS reflects most minor and major complications from a cost analysis perspective.

Based on the overhead cost method (indirect costs) the open surgery group had major costs related to the stay in the intensive care unit, representing $8501 (5575) compared with the percutaneous pulmonary valve implantation group where the postoperative costs were $876 (1087). Costs were substantially influenced by a few patients in need of a longer in-hospital stay than most of the patients in both groups. These patients were adults above 40 years, indicating that surgical treatment in

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grown-up congenital heart failure patients may be more costly than in children. This was also the case in patients treated with the percutaneous technique. The Spearman rank correlation analysis revealed a significant correlation between age and total LOS in both groups.

The percutaneous pulmonary valve replacement was significantly more costly than open surgery, even if the postoperative costs were significantly lower with the percutaneous technique. To get a full picture of the cost safety of the percutaneous technique, costs related to the first year after discharge should also be monitored.

In the study of Vergales *et al.* [18], doing a 5–10 year cost model, researchers found that percutaneous pulmonary valve implantation holds a significant cost advantage over the surgical approach, mainly because they estimated social cost savings in both groups in the analysis.

Because the sample size in our study population was small and not normally distributed we decided to perform bootstrapping along with parametric methods. Bootstrapping is a procedure to estimate the population distribution by using the information based on a number of resamples from the original sample. The bootstrap method creates a large number of datasets and computes the statistics on each of these datasets. We drew 1000 samples with replacement from the original sample and computed statistics (mean, median, SD, CI) for each bootstrap sample. Once we got a bootstrap samples created, we got distribution of the statistics.

The 95% bootstrap confidence interval is estimated by the cut-off values for the middle 95% of the bootstrap distribution. The mean of the bootstrap means was very close to the mean of the original sample. According to O'Hagan and Stevens [19], if parametric and bootstrap approaches show similar results, they should both be acceptable.

Strengths and limitations of the study

Strengths of our study are the prospective registration of data collection, allowing for the most precise level of microcosting as costs are recorded at the cost object level by counting every activity performed and transforming them into monetary units [16].

Limitations of the study were small patient populations influencing our statistical results. The results are not widely generalizable, as the data reflect the practice at a single centre, and the study is not randomized with a slightly different population in the study and the control group.

CONCLUSION

Although the mean device costs per patient were the main cost drivers in the patients receiving percutaneous pulmonary valve replacement, costs related to disposables, diagnostic tests and LOS in the intensive care unit and in the postoperative phase as a hole, were the main cost drivers in the patients receiving open heart pulmonary valve replacement. With a moderate reduction in the present device cost, the percutaneous technique may be cost saving from the hospital point of view as the technique holds the potential to reduce the postoperative costs significantly compared with open surgery.

Conflict of interest: none declared.

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