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Pringle manoeuvre versus selective hepatic vascular exclusion in partial hepatectomy for tumours adjacent to the hepatocaval junction: A randomized comparative study

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HIGHLIGHTS

- Compare the efficacy of SHVE versus Pringle manoeuvre in hepatectomy for tumours adjacent to the hepatocaval junction.
- SHVE is a safer method in partial hepatectomy for tumours which are adjacent or have invaded the hepatic veins.
- SHVE prevented profuse bleeding from hepatic vein injury, and reduced the postoperative complication rate.

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ABSTRACT

Objective: To compare the efficacy of selective hepatic vascular exclusion versus Pringle manoeuvre in partial hepatectomy for tumours adjacent to the hepatocaval junction.
Methods: A randomized comparative trial was carried out. The primary endpoint was intraoperative blood loss. The secondary endpoints were operation time, blood transfusion, postoperative liver function recovery, procedure-related morbidity and in-hospital mortality.
Results: 160 patients were randomized into 2 groups: the Pringle manoeuvre group ($n = 80$) and the selective hepatic vascular exclusion (SHVE) group ($n = 80$). Intraoperative blood loss and transfusion requirements were significantly less in the SHVE group. In the SHVE group, laceration of hepatic veins happened in 18 patients. Profuse intraoperative blood loss of over 2 L happened in 2 patients but no patient suffered from air embolism because the hepatic veins were controlled. In the Pringle group, the hepatic veins were lacerated in 20 patients, with profuse blood loss of over 2 L in 7 patients and air embolism in 3 patients. The rates of postoperative bleeding, reoperation, liver failure and mortality were significantly higher and the ICU stay and hospital stay were significantly longer in the Pringle group.
Conclusions: SHVE was more efficacious than Pringle manoeuvre for partial hepatectomy in patients with tumours adjacent to the hepatocaval junction.
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1. Introduction

In partial hepatectomy for hepatocellular carcinoma, the amount of blood loss is closely associated with postoperative mortality, complications and long-term prognosis. Limiting blood loss while performing safe and expeditious resection is the primary goal of liver surgery. Minimizing blood loss and blood transfusion can be achieved by various vascular clamping techniques, the selection of which is based on the location of tumour, the complexity of liver resection, the underlying liver disease and the patient's cardiovascular condition [1–4]. Selective hepatic vascular exclusion (SHVE) entails occlusion of hepatic vascular inflow and outflow of the liver using Pringle manoeuvre and extrahepatic clamping of major hepatic veins, while the blood flow in inferior vena cava (IVC) is still preserved. This results in total vascular isolation of the liver from the systemic circulation, but avoiding the haemodynamic and biochemical drawbacks associated with total hepatic vascular exclusion (THVE) [6–11] which involves Pringle manoeuvre and suprahepatic and infrahepatic clamping of IVC. SHVE can be total or partial, depending on whether the occlusion to

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the vascular outflow is for the whole liver or just for the right/left hemiliver. SHVE is considered by many surgeons to be hazardous. It is not widely used as laceration of hepatic veins during dissection may cause massive bleeding.

2. Methods

2.1. Study design

This randomized comparative trial (RCT) was approved by the Institutional Ethics and Review Board of the Eastern Hepatobiliary Hospital. Patient's decision to participate in the study was voluntary and informed consent was obtained before operation. The study was registered with the Australian New Zealand Clinical Trials Registry at http://www.anzctr.org.au and the registration number is ACTRN12611000962932.

From June 2008 to July 2010, 2300 patients received partial hepatectomy at the Third Department of Hepatic Surgery, Eastern Hepatobiliary Surgery Hospital. Only patients who met the following inclusion criteria were enrolled into this study: (1) patient who were surgically fit to receive partial hepatectomy; (2) resectable tumour which had invaded one or more major hepatic vein or was adjacent to the hepatocaval junction; (3) no other concomitant major surgical procedures such as bowel or bile duct resection; (4) no tumour invasion of IVC; (5) Child-Pugh Class A or B; (6) patient aged between 16 and 65 years.

2.2. Preoperative evaluation

All patients had a chest x-ray, ultrasonography, and contrast computed tomography scan (CT) or magnetic resonance imaging (MRI) of the abdomen. Laboratory blood tests including hepatitis B surface antigen, antibodies to hepatitis C, serum alpha-fetoprotein (AFP), carcinoembryonic antigen, carbohydrate antigen 19-9 (CA19-9), serum albumin, serum total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and prothrombin time were obtained, and the Pugh's modification of Child's criteria was determined. Further investigations were performed only when there was clinical suspicion of extrahepatic metastases.

2.3. Randomization

All eligible patients were randomly assigned to the Pringle manoeuvre and selective hepatic vascular occlusion group by drawing sealed, consecutively numbered, and opaque envelopes after abdominal exploration had confirmed resectability. The randomization was carried out by a nurse who was not involved in this study.

2.4. Surgical procedure

Surgery was performed through a bilateral subcostal incision. During surgery, the abdominal cavity was carefully searched for extent of local disease, extrahepatic metastases and peritoneal seeding. After mobilization of the liver, intraoperative ultrasound was performed to assess the number and the size of the lesions, and to assess the relation of the tumour to the vascular structures. The right adrenal vein was ligated to avoid bleeding during subsequent manipulation of the liver. The suprahepatic and infrahepatic inferior vena cava (IVC) and the porta hepatis were dissected and encircled with vessel loops. Aberrant arteries, if present, were controlled.

After complete mobilization of the right hemi-liver, the right and anterior aspects of the IVC were dissected by dividing the small hepatic veins which drained directly from the liver into the IVC. When a prominent right inferior hepatic vein was present, it was either encircled or ligated and divided according to its size and the type of liver resection that was about to be carried out. The hepatocaval ligament was dissected, transected and ligated. The right hepatic vein was then exposed and encircled with a vessel loop.

On the left side, after complete mobilization of the left hemiliver, the left upper aspect of the IVC was exposed by division of the peritoneal reflection above the caudate lobe. The ligamentum venosum was ligated and divided. The junction of the trunk of left/middle hepatic veins and IVC was dissected. In the majority of cases, the left and middle hepatic veins formed a common trunk outside the liver. The trunk was encircled with a vessel loop. In the minority of cases, the left and middle hepatic veins were separate extrahepatically. These veins were encircled with vessel loops individually.

After inflow occlusion with Pringle manoeuvre, the hepatic venous outflow occlusion was carried out in one of the following ways: (1) encircling and tightening the vessel loop in the ipsilateral hepatic vein or all hepatic veins; (2) clamping the ipsilateral or all hepatic vein(s) with hepatic vein clamp designed by the authors like a Satinsky clamp (Fig. 1).; using ultrasound to check whether the hepatic vein was occluded completely or not. (3) ligating extrahepatically the hepatic vein on the ipsilateral side of the hemiliver to be resected with 1-0 suture and controlling the other hepatic vein as in (1) and (2). The hepatic blood inflow was occluded by Pringle manoeuvre using cycles of clamp/unclamp intervals of 15/5 min. Liver transection was performed using the clamp-crashing technique. CVP was kept below 5 cm H_2O. After liver resection for the SHVE group, hepatic circulation was restored by successively releasing the occlusion to the hepatic vein(s), and then to the portal triad. Haemostasis was secured using 3-0 or 4-0 polypropylene sutures to plicate individual bleeding vessels on the raw surface of the liver.

2.5. Postoperative management

All patients received the same postoperative care by the same team of surgeons in the intensive care unit during the early postoperative period. Subsequent need for stay in the intensive care

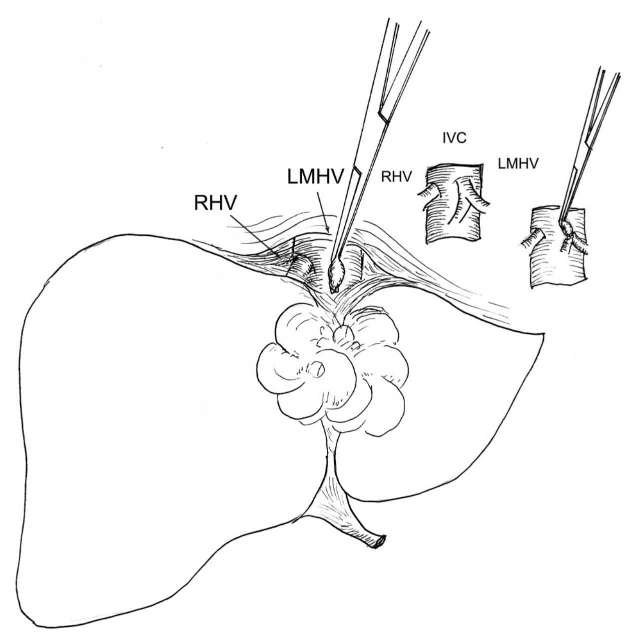
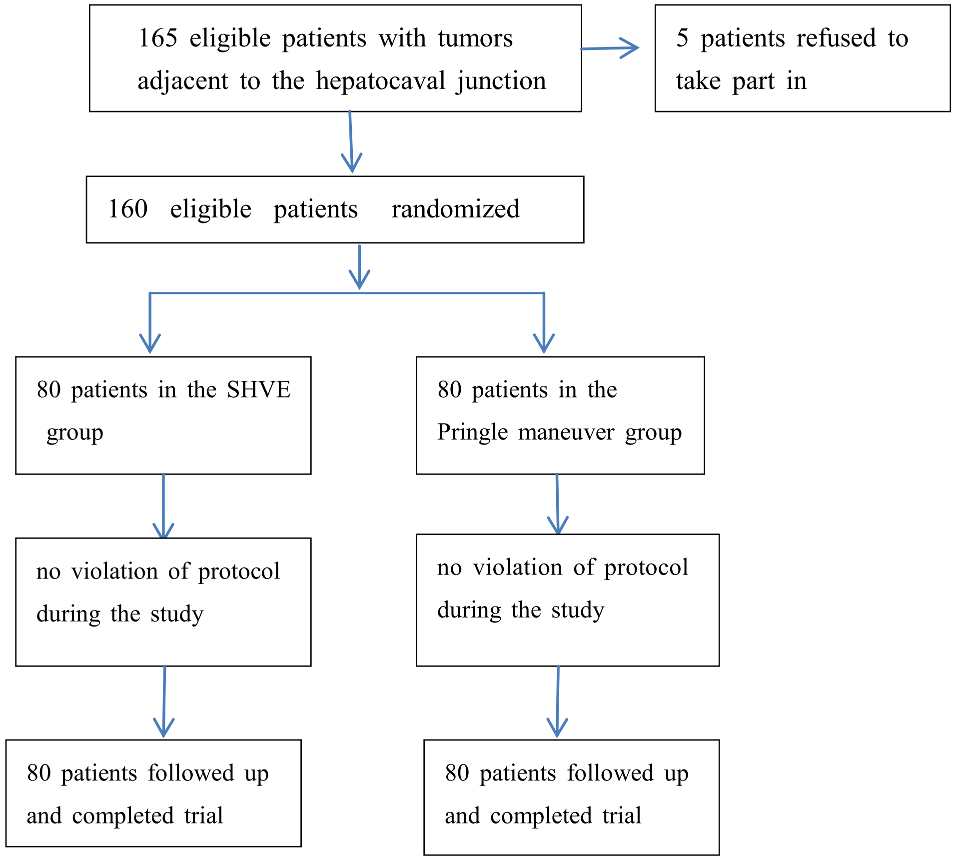


Fig. 1. The schematic diagram of clamping hepatic vein with a well-designed hepatic vein clamp.

Table 1
Trial profile.



unit was determined by the patient's condition. Liver function test and clotting profile were monitored .After the operation, haemoglobin level, coagulation profile, liver function and renal function were measured on postoperative days 1, 3, and 7. The Clavien-Dindo classification was used to report complications following liver resection [5].

2.6. Sample size calculation

According to the published literature [7], SHVE decreased 50% of blood loss in liver resection when compared with Pringle manoeuvre. Assuming a type-I error of 5% ($\alpha = 0.05$), a power of 80% for a 2-tailed log-rank test ($\beta = 0.2$), and a loss of 10% of patients on follow-up, the sample size was 160 patients, with 80 patients in each group.

2.7. Statistical analysis

The data were collected prospectively in a specially designed form for this study, which were then transferred to a computer database. The primary endpoint was intraoperative blood loss. Secondary outcome measures included operation time, blood transfusion, postoperative liver function recovery, procedure-related complications, and in-hospital mortality. Comparison between groups was made on an intention-to-treat basis. Continuous data were expressed as mean ± standard deviation (SD) or median (range) as appropriate. Comparisons between groups were performed by using the analysis of variance test. Categoric variables were compared by the chi-square test or the Fisher exact test. $P < 0.05$ was considered as significant.

3. Results

From June 2008 to July 2010, 165 patients were eligible for this study. Five patients refused to take part in the study, and 160

Table 2
Patient demographics and tumour characteristics.

	Pringle ($n = 80$)	SHVE ($n = 80$)	P
Age, mean ± SD	48.3 ± 9.2	49.2 ± 10.1	0.80
Sex (M/F)	63/17	61/19	0.31
Cirrhosis (n)	48	50	0.54
Liver functional status for cirrhosis (Child A/Child B)	43/5	45/5	
Preoperative laboratory tests			
Bilirubin (μmol/L)	16.6 ± 5.3	15.6 ± 5.7	0.70
Albumin (g/L)	41.0 ± 16.2	39.6 ± 15.8	0.53
Creatinine (μmol/L)	69.3 ± 28	72.6 ± 34	0.56
Pathology			
Hepatocellular carcinoma	58	60	0.80
Hepatocholangiocarcinoma	5	4	0.78
Colorectal metastases	4	3	0.69
Haemangioma	6	5	0.79
Hepatic adenoma	2	1	0.93
Focal nodular hyperplasia	3	4	0.95
Angiomyolipoma	2	3	0.91
Tumour size (cm)	8 ± 3.8	8.2 ± 4.0	0.76
Hepatic vein invasion			0.58
RHV	10	12	
RHV + MHV	23	24	
RHV + MHV + LHV	22	18	
MHV + LHV	18	16	
LHV	7	10	

Table 3
Types of hepatectomy performed.

Types of hepatectomy	Pringle ($n = 80$)	SHVE ($n = 80$)	p
Right hepatectomy	21	19	>0.05
Extended right hepatectomy	6	7	>0.05
Left hepatectomy	20	18	>0.05
Extended left hepatectomy	5	6	>0.05
Segment IV, V, VIII resection	5	5	>0.05
Segment VI, VII resection	3	2	>0.05
Segment VII, VIII resection	12	15	>0.05
Segment VIII resection	5	4	>0.05
Segment IV, I resection	3	4	>0.05

Table 4
Intraoperative data.

	Pringle ($n = 80$)	SHVE ($n = 80$)	P
Warm ischaemia time (min) (median [range])	25.7 (13–46)	24.4 (12–43)	>0.05
Operation time (min) (median [range])	138.4 (80–240)	131.2 (78–228)	>0.05
Blood loss (ml) (median [range])	776.9 (100–7000)	528.7 (100–2200)	<0.05
Blood transfusion (units) (median [range])	2.2 (0–30)	1.0 (0–12)	<0.05
Patients with blood transfusion (n)	22 (26%)	13 (16%)	<0.05
Patients with profuse loss of >2000 ml (n)	7 (9.1%)	2 (2.5%)	<0.05
Hepatic vein laceration (n)	20	18	>0.05
During hepatic vein dissection	0	1	
During liver transection	20	17	
Air embolism	3	0	
Change to THVE (n)	0	1	

patients were randomized into 2 groups: the SHVE group ($n = 80$) and the Pringle manoeuvre group ($n = 80$). There was no violation of protocol during the study (Table 1).

There were no significant differences between the two groups in age, weight, sex, tumour size, number of patients with cirrhosis, Pugh Child classification, warm ischaemia time and operating time ($P > 0.05$). There were also no significant differences in the types of hepatectomy and types of liver neoplasm (Tables 2 and 3). The Pringle group had significantly more intraoperative blood loss and required more blood transfusion (packed red blood cell) ($P < 0.05$). The incidence of laceration of hepatic vein(s) showed no significant difference (20/80 and 18/80). However, profuse intraoperative blood loss of more than 2 L occurred in 7 patients and air embolism in 3 patients in the Pringle group, compared with profuse blood loss of over 2 L in 2 patients and no air embolism in the SHVE group. For the 3 patients who suffered from air embolism, the right hepatic vein was torn in the first, the middle hepatic vein in the second and the left hepatic vein in the third patient. All these patients presented with a sudden drop in blood pressure, heart rate and oxygen saturation. The patients were actively resuscitated with inotropes, oxygen inhalation and the lacerations in the veins were compressed to control bleeding. SHVE was used in these three patients before the lacerations were finally controlled by suturing. Fortunately, no liver or renal dysfunction followed in these patients. In another 15 patients with active bleeding from lacerations from hepatic veins, conversion to SHVE was required before the bleeding sites were finally controlled with suturing. In the SHVE group, 1 patient required conversion to THVE because the tumour invaded the IVC. There were no other major intraoperative complications in the 2 groups of patients (Table 4). The postoperative complication rates were 29.7% in the Pringle group and 20.0% in the SHVE group (Table 5). Two patients in the Pringle group developed postoperative bleeding (>1000 ml), and 1 patient required a reoperation within 12 h of the first operation for haemostasis. There was no postoperative bleeding in the SHVE group. Liver failure occurred in 1 patient in the Pringle group. The ICU stay and the total hospital stay were significantly longer in the Pringle group than the SHVE group ($P < 0.05$).

The postoperative liver and renal functions in the two groups of patients are shown in Table 6. There were no significant differences on postoperative days 1, 3, 7 between the two groups in the total bilirubin (TB), ALT, albumin (ALB), pro-ALB, urea and creatinine.

Table 5
Postoperative complications.

	Pringle ($n = 80$)	SHVE ($n = 80$)	p
Patients with complications	17 (29.7%)	9 (20.0%)	<0.05
Pleural effusion	9	6	
Wound infection	4	3	
Postoperative bleeding	2	0	
Liver failure	1	0	
Reoperation	1	0	
Postoperative ICU stay	1.5 ± 1.0	1.2 ± 0.5	<0.05
Postoperative hospital stay	12.6 ± 4.8	9.8 ± 3.7	<0.05
In-hospital mortality	0	0	

4. Discussion

Adequate control of intraoperative bleeding is important during partial hepatectomy as it markedly reduces postoperative morbidity and mortality. Blood loss usually occurs during hepatic parenchymal transection and on reperfusion of the liver after Pringle manoeuvre. Pringle manoeuvre only controls bleeding coming from vascular inflow into the liver, but it cannot prevent backflow bleeding from hepatic veins. The amount of blood loss and the need for blood transfusion have a detrimental effect on the short- and long-term prognoses. During liver resection, an air embolus can occur as a consequence of a hepatic vein or the inferior vena cava being opened. This combined with sub-ambient pressure in the vein can result in a pressure gradient. Moreover, large air emboli can enter the heart and cause cardiopulmonary collapse. For operations on tumours which are large and adjacent to, or have invaded the major hepatic veins, massive bleeding and air embolism are possible consequences to laceration of hepatic vein(s) which are the most dreaded complications [1,3–6,12–15].

In this study, the amounts of intraoperation blood loss and blood transfusion were significantly higher in the Pringle group than the SHVE group because the Pringle manoeuvre cannot prevent backflow bleeding from the hepatic veins during partial hepatectomy [7,9,16–20]. Also in the Pringle group, laceration of hepatic vein occurred in 20 patients, with profuse intraoperative blood loss of over 2 L in 7 patients (amount of bleeding 2200 ml–7000 ml) and air embolism in 3 patients. In the SHVE group, the hepatic vein(s) was lacerated in 18 patients. However, as the hepatic veins were controlled, profuse intraoperative blood loss of over 2 L occurred only in 2 patients, and air embolism did not occur. The result of this study is similar to a previous study reported by the authors [7], and to a randomized controlled trial performed by Smyrniotis [6].

The rate of postoperative complication was significantly higher in the Pringle group than the SHVE group, with a resultant longer ICU stay and hospital stay. The results supported that the rate of postoperative complication is related to amounts of intraoperative bleeding and blood transfusion. There are two possible

Table 6
Laboratory data.

	Pringle ($n = 80$)				SHVE ($n = 80$)			
	Preoperative period	Postoperative			Preoperative period	Postoperative		
		Day 1	Day 3	Day 7		Day 1	Day 3	Day 7
Urea nitrogen (mmol/L)	4.6 ± 1.3	4.7 ± 1.2	5.2 ± 1.4	4.6 ± 1.6	5.6 ± 1.3	4.7 ± 1.4	5.7 ± 1.5	4.9 ± 1.7
Creatinine (mmol/L)	63 ± 112	65 ± 18	58 ± 12	52 ± 13	66 ± 13	62 ± 13	57 ± 14	59 ± 12
TBIL (μmol/L)	16.6 ± 5.7	24.7 ± 9.0	24.6 ± 9.2	18.5 ± 12.1	15.6 ± 5.7	24.6 ± 10.1	24.3 ± 11.8	16.9 ± 9.6
ALT (μ/L)	41.7 ± 32.4	735 ± 560	387 ± 246	112 ± 67.6	39.9 ± 29.0	715 ± 526	423 ± 403	106 ± 98
ALB (g/L)	41 ± 4.4	38 ± 3.2	36 ± 3.3	36 ± 3.2	46 ± 4.1	38 ± 3.2	35 ± 3.1	36 ± 3.3

explanations why there was an absence of a significant difference in the parameters of postoperative liver functional test between the 2 groups of patients in this study. First, the total vascular inflow with or without outflow occlusion was short, thus resulting in insignificant ischaemia-reperfusion injury to the liver remnants in these patients. Second, in the SHVE group, the majority of patients did not receive clamping of all the three major hepatic veins, thus there was still some blood perfusing the liver coming from the hepatic vein during SHVE.

SHVE has not been used by many surgeons as dissection of hepatic vein is widely considered as hazardous. The potential drawbacks of SHVE include difficulties in the isolation of major hepatic veins, as well as possible injury to these veins. If the liver tumour is large or has invaded the hepatocaval junction, mobilization and rotation of the liver would be difficult, making hepatic vein isolation and encirclement impossible using the conventional tourniquet technique. With our experience, the important anatomical sites should have a good command. Furthermore, It is not necessary to dissect the posterior wall of the right hepatic vein or the common trunk of the middle/left hepatic veins. And that it may not be necessary to dissect the hepatocaval ligament on the right, and the ligamentum venosum and lesser omentum on the left (Fig. 1). If there is any technical difficulty in completely isolating and encirculating the hepatic vein(s), the clamp method should be used. In this method, the anterior and lateral sides of the right hepatic vein and the common trunk of the middle/left hepatic vein are dissected. The fossa between the right hepatic vein and the trunk of the middle/left hepatic vein is then dissected. A clamp can be applied onto the right hepatic vein and another clamp onto the trunk of the middle/left hepatic veins. This clamping method is safer and easier as the posterior walls of the hepatic veins are not dissected. Clamping of the hepatic veins at their origins from the IVC effectively occlude the vascular outflow of the liver. As dissection of the liver from the IVC to isolate the hepatic veins is unnecessary, the time taken to control the hepatic vein(s) is shorter than the other methods. In the SHVE group in this study, there was only one incidence of laceration of hepatic vein during hepatic vein dissection. The laceration was repaired easily as application of a clamp on the hepatic vein successfully prevented major bleeding [6,10,12,21,22]. As liver tumour not infrequently invades hepatic vein(s) inside the liver, SHVE plays an important role in partial hepatectomy for these patients.

In conclusion, the study showed SHVE to be a safer and more efficacious method than the Pringle manoeuvre in partial hepatectomy for tumours which are adjacent or have invaded the hepatic veins. SHVE prevented profuse bleeding from hepatic vein injury, and reduced the postoperative complication rate.

Ethical approval

We regretfully omit to acquire the ethical approval.

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Author contribution

Fu Si-Yuan and Zhou Wei-ping designed, analyzed and wrote the paper, Lau Wan Yee and Wu Meng-Chao provided critical suggestion and revised the manuscript, Yang Yuan, Yuan Sheng-xian, Wang Zheng-guang and Huang Gang collected the clinical data.

Conflicts of interest

None declared.

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