Background: Femoral venous and arterial approaches are the commonly used to obtain vascular access for pediatric cardiac catheterization. Hemostasis after catheter removal is usually obtained by manual compression. However, this technique is time consuming and at times painful. Although several closure devices are available for adults, they are not widely applicable in children. Objectives: To evaluate the safety and efficacy of a microporous polysaccharide hemospheres hemostasis (MPH) bandage compared to manual compression. Methods: Prospective randomized study, involving 112 children after cardiac catheterization. One group received the MPH bandage, another manual compression. Compression time was predetermined by the size of sheath plus one minute. Success was defined as no bleeding or hematoma formation. If bleeding continued, compression was continued as needed and time to hemostasis recorded. Informed consent was obtained prior to randomization. Group comparisons were performed with a Student’s $t$, Pearson’s Chi Square, and Fisher’s exact test as appropriate. Results: Fewer children required a compression time of >15 min ($P = 0.006$) and more had a shorter time to hemostasis ($P = 0.003$) in the MPH group for venous access control. Time to hemostasis was also shorter in the MPH ($P = 0.048$) in arterial access cases, but the number of children requiring a compression time >15 min was the same. Complications including hematoma formation in each group were similar. Conclusions: The MPH bandage allows a shorter time to achieve hemostasis compared to manual compression. This improves turnaround time and laboratory efficiency.

Key words: pediatric interventional cardiology; hemostasis; closure devices

INTRODUCTION

Percutaneous cardiac catheterization is associated with the risk of vascular access site complications, with the femoral approach most commonly used in children. Although serious bleeding rarely occurs after transfemoral access, the incidence of bleeding or hematoma ranges from 0.005 to 0.006% in children [1,2]. Manual compression is the standard for achieving local hemostasis at the puncture site. However, this technique is time consuming, at times painful for the children and it potentially can induce a vasovagal reflex with a drop of blood pressure and heart rate. Further, time to arrest bleeding requires prolonged immobilization, decreasing laboratory turnaround time and increases anesthetic time, all of which have cost implications. Several studies have shown that the use of closure devices after diagnostic and interventional catheterization in adults is safe [3–6]; however, their routine application is limited in children and only after larger French-sized venous access [7]. To this end, we evaluated a microporous polysaccharide hemospheres hemostasis bandage (MPH) (Arista and Hemaderm, Medafor, Minneapolis, MN) that could be applied after routine vascular access.
in children. To our knowledge, the use of MPH after pediatric cardiac catheterization has not been assessed compared to standard manual compression.

METHODS AND MATERIALS

The Bandage

The MPH contains a novel absorbable agent that has been shown to be effective for hemostasis in cardiac, urologic, and dermatologic surgery [8–11]. MPH particles are produced from purified potato starch and act as a molecular sieve to rapidly extract fluids from blood. This osmotic action causes the microporous particles to swell and concentrate serum proteins, platelets, and other formed elements on their surfaces. The spherical particles, with diameters ranging from 30 to 100 µm and their coating of compacted cells, create scaffolding for the formation of a clot [12].

The Children

A prospective, randomizing study was designed to include all children undergoing diagnostic or interventional cardiac catheterization. The institutional ethics review board approved the study and all parents were approached for consent and randomization, except those where the clinician anticipated using a suture-mediated closure system. Randomization was performed using the last digit of the child’s hospital number and randomized either to a MPH bandage group or manual compression group prior to the catheterization.

Catheter Procedure

All catheterizations were performed under general anesthesia. The children’s groins were prepared with a liquid butadiene scrub or those with an iodine allergy with chlorhexidine. Vascular access was achieved using a modified Seldinger technique. Sheath sizes from 4 to 13 Fr. were used for femoral access. Most frequently used puncture needles were a “butterfly” needle (Surshied 21 G, 3/4”, Terumo Medical Products Hangzhou, Hangzhou, China) in neonates; Cook puncture needle (Percutaneous Entry Thin wall needle 21 G, 3 cm, Cook Medical, Bloomington, US) or Percutaneous Entry needle 21 G, 5 cm, Cook Medical Inc., Bloomington, US) in those 20 kg or less, and a larger gauge needle (Introducer, Syringe Needle 18 G, 7 cm, Inra, Kentwood, US) in those >20 kg in weight. Arterial access was, when possible, obtained through a single anterior wall puncture in the femoral artery. In the majority of those cases (primarily venous access) heparin sulfatate (50–150 IU/kg, maximal dose 5,000 IU) was administered intravenously after vascular access was achieved. Heparin sulfate was reversed at the discretion of the operator in cases where the sheath size was >8 Fr. and the ACT at the end of case was >220 sec.

Hemostasis Protocol

The sheath was removed under manual compression on the common femoral artery or vein proximal to the skin incision after the conclusion of the case. In the MPH group, the bandage was then placed at the skin puncture site and manual compression applied. Compression time was determined as size of sheath plus 1 min. For example, if a 7-Fr. sheath was used, then the compression time was 8 min. Success of hemostasis was defined as no bleeding or hematoma formation after release. If bleeding continued, compression was continued for an additional minute. The site was the rechecked and an additional minute of pressure applied. This continued until no bleeding was noted, and the total time recorded as the time to hemostasis. In the manual compression group, hemostasis was obtained by direct digital pressure. The same formula for compression time and time to hemostasis was applied in this group. All children were kept supine bed rest for 4 hr after hemostasis if they had an arterial sheath. In venous puncture cases alone, children were kept in supine bed rest for 3 hr. We assessed the integrity of the vessels and confirmed the presence or absence of thrombus in the vessel, hematoma around puncture site by ultrasonographic examination within 24 hr of the procedure.

Statistics

Data are presented as means with standard deviations unless otherwise specified. Pearson’s Chi Square and Fisher’s exact test were used for comparison of categorical data, and the two-tailed Student’s t-test was used to compare continuous variables. A power calculation (α = 0.05, β = 0.2) to detect a difference between groups in the proportion requiring >15 min to achieve hemostasis determined that 45 children were required in each group. A P-value of ≤0.05 was considered statistically significant.

RESULTS

Demographic Characteristics

Fifty-two children (46.4%) were in the MPH group and 60 (53.6 %) randomized to the manual compression group (Tables I and II). Table III shows the sheath sizes employed during the procedures. There were no significant differences between groups regarding
baseline characteristics, although the majority of venous sites cannulated in the MPH group were during interventional procedures. There was no significant difference found between groups (Tables I and II) when comparing age, proportion of males, height, weight, procedure time, sheath size, and dose of heparin sulfate. Similarly, there was no significant difference between groups (for venous access sites)
regarding the activated clotting time (ACT) (average 187.2 ± 18.6 vs. 194.4 ± 39.7 sec, \( P = 0.71 \)).

**Efficacy of Hemostasis**

Hemostasis was achieved in all cases. In venous access cases, significantly fewer MPH group children required a compression time of >15 min (5 vs. 17 cases; \( P = 0.006 \)) as well as a shorter time to hemostasis (10.9 ± 3.8 vs. 15.8 ± 9.6 min, \( P = 0.002 \)) compared with the compression group. Time to hemostasis after arterial access was also significantly less in the MPH versus compression groups (8.3 ± 6.0 vs. 17.2 ± 10.9 min; \( P = 0.048 \)). However, there was no significant difference in the number of children requiring a compression time of >15 min.

**Complication Rate**

Vascular integrity was assessed by ultrasonographic examination in 94 of 112 children (84%) to determine the presence or absence of thrombus before discharge from hospital. Forty-five children in the MPH group (venous puncture; 37 cases, arterial puncture; 8 cases) and 49 were in the control group (venous puncture; 38 cases, arterial puncture; 11 cases) were examined. The incidence of hematoma and rebleeding in the MPH for either venous or arterial access cases was not different when compared to the control group (hematoma; 4 vs. 4 cases, \( P = 0.79 \), rebleeding; 8 vs. 3 cases, \( P = 0.16 \)). The same was true for arterial access cases (hematoma; 1 vs. 3 cases, \( P = 0.98 \), rebleeding; 1 vs. 3 cases, \( P = 0.98 \)) (Tables I and II). No intraluminal thrombosis was identified by ultrasound in either group.

**DISCUSSION**

In 1951, the Seldinger technique was introduced reducing the risk of hemorrhage from vessel entry [13] with manual compression the primary means of achieving hemostasis for nearly 40 years. Vascular closure devices were first developed in 1990’s and in recent years, several different types of such closure devices have become available for adults [6,14–17]. However, most are not applicable in children, particularly as applied to smaller Fr-sized sheaths. As such, manual compression was the only technique available and often prolonged, when due to coadministration of heparin sulfate. In this regard, we were interested in determining if manual compression could be shortened with an adjunctive device, that in itself would not compromise the smaller vessels accessed in the child. The MPH bandage in this study, compared to manual compression, was found safe in the management of the pediatric vascular puncture site and hemostasis successfully obtained in all cases. No significant complications occurred and vascular compromise was not observed. Although, both MPH and control groups developed hematoma and rebleeding in some cases, there was no significant difference between groups (Tables I and II). The MPH bandage significantly reduced the number of children requiring a compression time of >15 min and the time to hemostasis in venous access cases, and the time to hemostasis in arterial access cases. There were too few arterial entries (8 vs. 13 MPH and controls respectively) to comment on the efficacy of the MPH patch for arterial sites. As such, the bandage can be used to augment standard manual compression to reduce turnaround time and improve the efficiency and productivity of the laboratories. Published data also suggest that some vascular closure devices are associated with high complication rates when compared to standard manual compression in adults [14]. In that respect, the MPH bandage is easy to handle, virtually without a learning curve and repuncture is not a problem, with a reduction in time to hemostasis by about 5 min.

In summary, this is the first randomized prospective study comparing the MPH bandage for vascular hemostasis to manual compression in children. We found that the bandage was safe, effective with a reduced time to hemostasis and lower number of children requiring prolonged compression, particularly for venous access applications. The frequency of complications was not significantly different from the conventional manual compression, although a larger study may be required to determine if a difference is present.

**REFERENCES**


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