Journal of Pediatric Surgery 51 (2016) 1747–1750

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

Original Articles

Complications in using the vertical expandable prosthetic titanium rib (VEPTR) in children

John H.T. Waldhausen [a,*], Greg Redding [b], Klane White [c], Kit Song [c]

[a] Division of Pediatric Surgery, Seattle Children's Hospital, University of Washington School of Medicine, Seattle, WA
[b] Division of Pulmonary Medicine, Seattle Children's Hospital, University of Washington School of Medicine, Seattle, WA
[c] Department of Orthopedics and Sports Medicine, Seattle Children's Hospital, University of Washington School of Medicine, Seattle, WA

ARTICLE INFO

Article history:
Received 8 January 2016
Received in revised form 13 June 2016
Accepted 19 June 2016

Key words:
Vertical expandable prosthetic titanium rib (VEPTR)
Chest wall reconstruction
Thoracic insufficiency syndrome (TIS)
Scoliosis

ABSTRACT

Purpose: This report describes complications using the vertical expandable prosthetic titanium rib (VEPTR) for thoracic insufficiency syndrome (TIS) at a single center.
Methods: This is a prospective cohort evaluating 65 patients with rib–rib and rib–spine VEPTR devices for TIS placed between 10/2001 and 11/2014, for children with spinal or chest wall deformity. Patients were classified using the early onset scoliosis classification system (C-EOS).
Results: 65 patients are available for follow up. 23 congenital scoliosis, 12 neuromuscular, 14 syndromic, 2 idiopathic and 14 not classifiable by the C-EOS system including 11 chest wall reconstructions. Average age at implantation was 6.9 years (range 1.3–24.8) with average follow up 6.9 years (range 0.4–14.8). 22 patients had 37 complications. Those classifiable by C-EOS had complications in the normo- and hyperkyphotic groups. Implant erosion and infection were most common. The majority of complications required one additional unplanned surgery for resolution. Two complications required abandonment of a growth-friendly strategy.
Conclusions: Use of VEPTR for TIS is associated with significant and frequent complications. C-EOS suggests that complications are more likely in those with normal or hyperkyphotic curves. Most complications are managed with one unplanned surgery. VEPTR is usually salvaged and abandonment of a growth-friendly strategy is unusual.

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Thoracic insufficiency syndrome (TIS) is a devastating problem that may lead to respiratory insufficiency and for some children, death. TIS is a spectrum of thoracic conditions leading to the inability of the thoracic cavity to function normally to provide adequate respiration. The vertical expandable prosthetic titanium rib (VEPTR, DePuy Synthes, West Chester PA) was developed by Drs. Robert Campbell and Melvin Smith to help treat this disorder [1]. Prior to the development of this device, any method used to treat spinal and chest wall deformity was hampered by the inability of the repair to be adjusted for growth of the child. VEPTR was developed because it can be adjusted for growth and its use in some studies has been shown to improve the respiratory function for many of these children [2,3]. Our hypothesis is that VEPTR is associated with significant but not insurmountable complications and treatment goals are achievable despite these complications. This report reviews our experience with complications and the use of this device using the C-EOS system to classify patients' conditions where applicable and a newly published categorization of complications as described by Smith [4,5].

1. Methods

This is a report of a prospectively evaluated cohort of 65 patients treated for thoracic insufficiency syndrome using VEPTR at Seattle Children's Hospital between 10/2001 and 11/2014. All 65 patients are available for follow up. All appropriate patients were classified using the early onset scoliosis classification system (C-EOS) described by Williams et al. [4] In addition, all complications are classified by the system described by Smith et al. [5] This review includes children with associated conditions where preexisting underlying lung disease in addition to spinal or chest wall deformity contributed to morbidity, e.g. congenital diaphragmatic hernia.

This report includes use of VEPTR I and VEPTR II rib-to-rib and rib-to-spine devices as well as modified VEPTR devices. VEPTR II devices were used after they became available in 2008 because of their increased versatility with the ability to use different lengths of the device both proximal and distal to the expansion clip. In addition, VEPTR II had increased options for cradle attachment and had modifications to minimize breakage. Spine–spine VEPTR devices used as growing rods for scoliosis are not included in this study.

Abbreviations: TIS, thoracic insufficiency syndrome; VEPTR, vertical expandable prosthetic titanium rib; C-EOS, early onset scoliosis classification system.

* Corresponding author at: Seattle Children's Hospital, 4800 Sand Point Way NE, Seattle, WA 98105. Tel.: +1 206 987 1177; fax: +1 206 987 3925.
E-mail address: john.waldhausen@seattlechildrens.org (J.H.T. Waldhausen).

http://dx.doi.org/10.1016/j.jpedsurg.2016.06.014
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Inclusion criteria for VEPTR placement are similar to those in our prior report in 2007 [2]. These include evaluation and acceptance by all three services pulmonary, orthopedics and pediatric general surgery. Patients had to have TIS as defined by Campbell et al. [1] secondary to flail chest, congenital restrictive chest wall syndromes or progressive spinal deformity. Patients had to have adequate superior and/or inferior native ribs or vertebral bodies for VEPTR attachment. All patients had to have adequate soft tissue for VEPTR coverage defined as 2 cm of skin and soft tissue in a pinch test and all had to be in such condition as to tolerate a major thoracic procedure. Inadequate soft tissue coverage excluded patients until such tissue via nutritional support or tissue expanders could be obtained. We preferentially used nutritional support using gastrostomy tubes or nasogastric feeding tubes with the exception of the very young child in whom it was felt adequate tissue coverage by nutritional support alone would be inadequate. Patients needed to be able to undergo multiple anesthetics to allow VEPTR expansion and had to be able to travel to our hospital for this expansion to occur. Any child who met the above criteria was accepted for treatment as there was felt to be no viable long-term alternative and it was felt unethical to withhold treatment. Patients were not randomized for this reason.

The technical aspects of device placement have been previously described by us as well as others [1,2]. All patients had neurophysiological monitoring. This was performed using somatosensory evoked potentials (SSEPs), transcranial electrical motor evoked potentials (MEPs) and spontaneous electromyography (sEMG).

The VEPTR was initially approved for use under a humanitarian device exemption from the Food and Drug Administration (FDA). This humanitarian exemption is no longer in effect and the VEPTR is FDA approved for clinical use. This review was approved by our Institutional Review Board. The authors have no financial or other conflicts of interest to disclose regarding the use of the VEPTR.

2. Results

65 patients had their initial operation for VEPTR placement for thoracic insufficiency syndrome and associated conditions from 10/2001 to 11/2014 at our institution. All 65 were available for follow up. This series includes 35 patients with VEPTR I implants and 30 patients with VEPTR II implants. VEPTR I was used in all rib-to-rib constructs and all rib–spine patients prior to 2008 when VEPTR II became available. Patients included 23 with congenital scoliosis, 12 with neuromuscular scoliosis, 14 with syndromic TIS, 2 with idiopathic scoliosis and 11 who had chest wall reconstructions for oncologic and other reasons. 3 other patients in addition to the chest wall reconstructions could not be classified by the C-EOS system because preoperative films were no longer available. The average age at implantation was 6.9 years (range 1.3–24.8 years) with an average follow up of 6.9 years (range 0.4–14.8 years). Patients had an average of 5.5 expansions. For those with scoliosis, 28 have gone to definitive fusion. Associated conditions included ventilator dependence, congenital diaphragmatic hernia, arthrogryposis, VACTERL association, flail chest, fused ribs, meningomyelocele, nutritional deficiency, severe kyphoscoliosis, Jeune, Conradi–Hunermann and Poland syndromes, osteosarcoma, Ewing sarcoma, desmoid tumors, and myopathy. There has been one death during the follow up period in a teenager with osteosarcoma because of his oncologic disease.

The C-EOS classification system was used to classify patients, except for those whose ages were more than 10 years and those with chest wall resections as C-EOS is not applicable for these groups (Table 1). All but one of our scoliotic patients had curves >51°. Of those patients classifiable by C-EOS, all but one complication occurred in patients with hyperkyphotic (+) or normokyphotic (N) curves. There was no clear difference in complications across etiologies as the numbers are small. Of those with congenital (C) scoliosis, 21.7% had complications, while those with neuromuscular (M), syndromic (S) and idiopathic (I) each had 58.3%, 28.5% and 50% complications, respectively. Those not classifiable by C-EOS had a 35.7% complication rate.

Table 1
C-EOS patient classification (etiology/scoliosis/kyphosis*).

(Classification/number of patients/# patients with complications)												
C 2 N	1	1				S 3-	1	0			
C 3 N	9	2	M 3 N	3	2	S 1 N	3	0	I 3 N	1	0
C 3 +	6	1	M 3 +	4	2	S 2 N	1	0	13 +	1	1
C 3 -	1	0	M 3 -	1	1	S 3N	3	0	Other	14	5
C 4 +	4	0	M 4 +	4	2	S 3 +	4	2			
C 4 N	2	1				S 4 +	2	2			

Etiology	Scoliosis	Kyphosis
C: congenital or structural	Group 1: major curves <20°	N: normokyphotic range 20–50°
M: neuromuscular	Group 2: 20–50°	(+): hyperkyphotic
S: syndromic	Group 3: 51–90°	(−): hypokyphotic
I: idiopathic	Group 4: >90°	NA: not applicable to C-EOS

Complications related to the VEPTR are frequent and are nontrivial. These complications were analyzed using a classification system reported by Smith et al. [5] (Table 2). Complications are reported as disease or device specific and then with grades of severity and whether treatment goals were met or not (Table 3). Of the 65 patients, 22 had a total of 37 complications. Of these complications, groups 3 and 4 in the C-EOS system accounted for all but one complication. 12 patients had one complication, 8 had 2 complications and 3 had 3 complications. There was one death. Most of these complications were Grade IIA, device related, and required one additional surgery for resolution. Only 2 patients lost the VEPTR because of complications and had to go to early fusion. Twelve children (18.5%) had migration of either the superior cradle hook or the inferior fixation. One of these children (1.5%) had failure of the spinal fixation screws. Two children (3.1%) had migration of the sacral S hook into the pelvis. The other 9 had migration of the superior cradle (13.8%). All of these children either required VEPTR revision or were at a point in treatment that they underwent VEPTR removal and final spinal fusion. Nine patients (13.8%) had wound infections though only 1 (1.5%) of these was related to the primary implantation. The 8 others (12.3%) were in individual patients occurring in reoperative wounds used for VEPTR expansion or replacement. All of these were culture positive for skin flora and 2 required implant removal. The one initial infection was in a lateral thoracostomy incision. All others were in either reoperative paramedian or midline incisions. Two of the 9 children (3.1%) had skin breakdown/dehiscence during the course of the treatment, both in reoperative wounds for VEPTR expansion or revision. Neither of these required implant removal. Five children had intraoperative somatosensory evoked potential (SSEP) changes though no postoperative neurologic changes were found. One additional child developed a postoperative radiculopathy that resolved over time. Three patients had implant fracture, 1 from the VEPTR itself and 2 from the intramedullary wire placement (4.6%) used in our early patients to provide extra rigidity to the chest wall. Three of the 11 patients who

Table 2
Complications classification system.

Grading	Device related	Disease related
I	Does not require unplanned surgery	Outpatient medical management only
II		Inpatient medical management
IIA	Requires 1 unplanned surgery	
IIB	Requires multiple unplanned surgeries	
III	Requires abandoned growth-friendly strategy	Requires abandoned growth-friendly strategy
IV	Death	Death

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