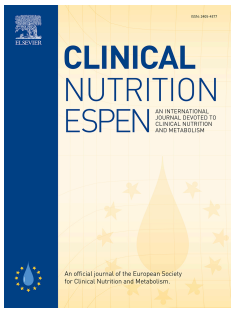

Non-conventional Vascular Accesses for the management of Superior Vena Cava Syndrome in Patients with Intestinal Failure. *Case Series and Systematic Review*

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Non-conventional Vascular Accesses for the management of Superior Vena Cava Syndrome in Patients with Intestinal Failure. *Case Series and Systematic Review.*

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ABSTRACT

Background. Type III Intestinal Failure (IF) is a devastating clinical condition characterized by the inability of the gut to absorb necessary macronutrients, and/or water and electrolytes, requiring Parenteral Nutrition (PN) as chronic therapy. Long-term PN may lead to life-threatening complications; the loss of central venous access (LCVA) is the most frequent and challenging. To date, few studies in the literature have reported the relevance of Non-conventional Vascular Accesses (NCVA) in the management IF as part of the comprehensive multidisciplinary care.

Methods. A retrospective analysis of a database collected from January 2006 to December 2019 was performed using SPSS v25.0 for statistical analysis, followed by a systematic review, using the PRISMA methodology.

Results. From January 2006 to December 2019, 184 NCVA were placed in 71 patients with LCVA as IF-related complication; 173 were placed in 61 patients by interventional radiology (IR) and 11 NCVA were placed in 10 patients by the surgical team during the intestinal transplant (ITx) operation. From the 173 IR procedures 166 (95.9%) were successful with 3 ± *2.7* procedures/patient; average catheter permanence rate was 738.68 ±*997* days; complications related to the procedures occurred in 18/173 (10.4%), including two deaths. On the other hand, among the 11 NCVA implanted by the surgical team, 7 (64%) were successful and were safely withdrawn 30 days after ITx when were no longer needed; 2 (18%) catheters malfunctioned during the first week and could not be further used, and 1 was accidentally removed; average catheter permanence rate was 26 ± *4* days. There was one complication (9%) requiring laparotomy; there was no mortality associated the procedure in this group. A

systematic review was conducted to evaluate the success and safety of NCVA as part of the treatment of HPN-related complications; from 337,542 papers, 14 studies were included. A total of 28 HPN-patients with LCVA received NCVA; 34 procedures were successfully performed, while procedure-related complications were reported in 11.7%, as well as one death.

Conclusions. The data analyzed show that NCVAs may be successfully placed by expert teams, allowing to sustain long-term PN, as well as increasing the Intestinal Transplantation applicability for candidates in the extreme need of vascular access.

Keywords. Small bowel, Loss of vascular accesses, interventional radiology, superior vena cava syndrome**,** home parenteral nutrition complications.

INTRODUCTION

Type III Intestinal Failure (IF) is a devastating condition defined as the inability of the gut to absorb macronutrients, water and electrolytes[1]. The incidence varies from 5 to 20 cases per million population, and the range is even higher in emerging and non-emerging economies[2]. The etiology includes a group of conditions, short bowel syndrome (SBS) and chronic intestinal pseudo-obstruction (CIPO) (74.7% adults – 52.4% pediatric, and 18% adults – 22.9% pediatric respectively) are the most common in both, adults and children [1][3].

The current guidelines show that the best outcome is obtained when treatment is designed, provided, and followed by a multidisciplinary team able to offer from parenteral nutrition (PN) support to intestinal rehabilitation, and intestinal transplant (ITx) when necessary [1]. The gold standard therapy is home PN, but it is well-known that long-term replacement therapies may cause problems leading to life-threating complications. Catheter-related infections and thrombosis are the most common causes of loss of central venous access (LCVA) sites. The CDC frequency rate accepted for infections in specialized units is 1-4/1000 days[4]. The incidence of mechanical events such as occlusion, leakage and dislodgement in different series is 3.37 per 1000 days-catheter, whereas the incidence of CVC-related thrombosis in children with different diseases is 3.5/100,000 hospital admissions [5-7].

As of 2012, the leading indication for ITx was IF associated liver disease [8]. The multidisciplinary management, improvement and reduction of the frequency and severity of catheter related sepsis, and the optimization of the PN regimen

have had a positive impact on the rate of liver injury [8]. Since then, the primary indication for ITx evaluation is LCVA [4-8].

LCVA is not a complication exclusively related to long-term PN; some patients with Chronic Kidney Disease (CKD) on hemodialysis (HD) also face the same life-threatening risks [9-19]. The need to maintain vascular patency in Type III IF patients has led to search for new endovascular, surgical or hybrid techniques (Supplementary Table 1) [20].

In this paper, we will refer to common vascular accesses as “conventional vascular accesses”, and alternatives as “unconventional or non-conventional vascular accesses” (NCVA) [21-22], (Table 1), defined as all vascular accesses that required catheter-directed thrombolysis, balloon angioplasty and/or stenting, need to implant catheter in alternative veins, or placement through a direct approach, anterograde/retrograde recannulation, or venotomy [23-32].

Conventional Accesses	Non-Conventional Accesses	Last Resource Accesses
Jugular	Azygous	Transhepatic
Subclavian	Translumbar	Direct right atrial insertion
Femoral	Intercostal veins	Gonadal vein*
	Percutaneous mammary	
	Arteriovenous fistula	

Table 1. Type of access for HPN modified from the ESPEN Guidelines and having in consideration the ISBTS 2015 CVA workshop. **Mainly used and accessed during the engraftment in order to have post-ITx vascular accesses.*

To the best of our knowledge, few studies have reported the long-term experience addressing diagnosis, management, or endovascular techniques used to recover central accesses in IF patients. Therefore, this study aims to describe a multidisciplinary experience to manage LCVA as a consequence of long-term PN at a single center and carries out a systematic review to evaluate the success and safety of NCVA as part of IF-related complication treatment.

MATERIAL and METHODS

Case series

This single-center study was based on a retrospective analysis of a prospective database of patients with type III IF on home PN requiring at least one NCVA placement or replacement at the Interventional Radiology unit (IR), or NCVA placed by the surgical team during intestinal engraftment at our center from January 2006 to December 2019.

- *Inclusion criteria:* type III IF pts evaluated at our Unit with LCVA as PN-related complication requiring fluoroscopy-guided NCVA placement

- *Exclusion criteria:* patients without type III IF, or NCVA implanted with an indication different than PN infusion.

Variables analyzed:

a. Demographic data and medical information were obtained from a computerized database and medical records. For each pt, data on gender, age, access date, percutaneous intervention date, technique used, type of catheter, success rate, procedure-related complications, average catheter permanence rate, death, and transplant as general variables were analyzed.

b. Technical variables were divided according to puncture site and the type of technique used. The radiological approach was subdivided based on the use of collateral veins, alternative sites, or salvage sites.

Systematic Review

1. ***Protocol:*** A systematic literature review was carried out to identify available evidence providing information on the NCVA for the treatment of PN-related complications according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses guideline [33].

2. Eligibility Criteria:

- ***2.1 Study design:*** Clinical trials such as randomized-controlled trials, controlled clinical trials, prospective and retrospective comparative cohort studies, case-control studies, cross-sectional studies, case series, and case reports were included.
- ***2.2 Publication Status:*** Articles published in scientific journals were collected.
- ***2.3 Languages:*** Only papers written in English were considered.
- ***2.4 Outcomes:*** The outcomes of interest were catheter average patency rate, catheter-related complications, other complications, and mortality.

3. Information sources: A search strategy was developed, and the following databases were explored: PubMed, Embase, and Medline to identify completed and ongoing studies as of 20 August 2020. In addition, we also searched for the reference lists of the articles selected.

4. Search strategy: Mesh search was performed to cover the following terms “veins”, “thrombosis”, “catheter”, “parenteral nutrition, home”, “Central Venous / methods”, “Catheters, Indwelling”, “Radiography, Interventional”, “Axillary Vein / injuries”, “Angiography, Digital Subtraction”, “Catheter Obstruction”, “Catheterization, Central Venous / adverse effects”, “Phlebography / methods”, “Vena Cava, Superior / abnormalities”, “Vena Cava, Superior / diagnostic imaging”. Given the scarcity of useful information about the main-related search, it was extended to the following keywords “non-conventional vascular access”, “unconventional vascular access”. The filters applied were: Human, English language. Papers or information whose main topic was different from those established by our research objective were excluded. The results of our database searches were documented. In case of duplicated data, the most recent article was included. Removal of duplicates was also done manually and depicted in a PRISMA flow diagram.

5. Study selection: A study screening was done with a minimum of three authors from the search results; authors independently screened the titles and abstracts of studies using the inclusion criteria. Studies selected at title and abstract levels were screened further with the full text of the article for eligibility to include in our review.

6. Data collection process and data items: A pre-conceived data extraction sheet was used to obtain data from selected eligible studies. Any consensus in case of disagreement was set by the opinion of the majority. The extracted

information included number of pts, number of procedures, who performed the procedure (service or unit), age of pts, etiology of type III IF, technique used, follow-up time, average patency rate, complication rate, and mortality. The results of our database search were documented and described in a PRISMA flow diagram.

7. Risk of bias in individual studies: To reduce the risk of bias, three independent authors assessed the included studies. The overall risk of bias was judged as low risk, unclear risk, and high risk.

***Statistical analysis*.** Continued variables were expressed as mean ± standard deviation (SD). Categorical variables were expressed as “N” and percentages. Fisher's exact test, Chi-test and t test were used; accordingly, the statistical analysis was conducted using IBM statistical package for social science (SPSS v25)®.

RESULTS

SINGLE-CENTER SERIES

General Variables. From January 2006 to December 2019, 184 NCVA were placed in 71 patients who presented LCVA as IF-related complication; 173 of them were placed in 61 patients by IR and 11 NCVA were placed in 10 pts by the surgical team (Figure 1).

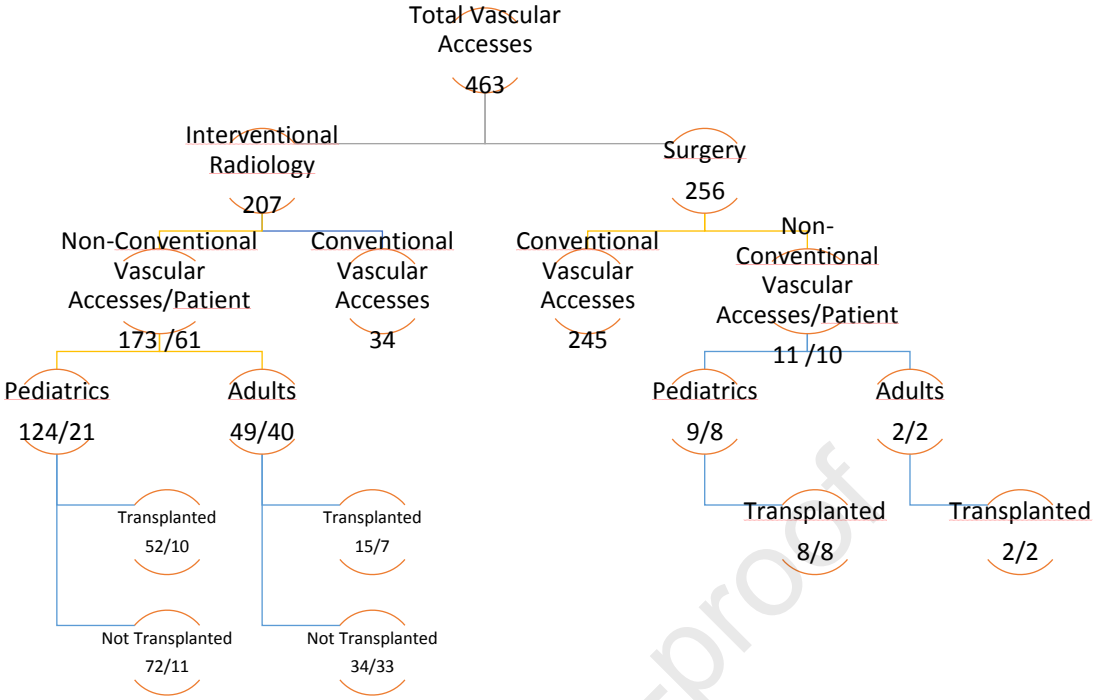

Figure 1. Single Center Database of all the accesses implanted in IF patients from 01/2006 to 12/2019.

Among the 173 procedures performed by IR, 124 (71.7%) were done in pediatric patients. The patient's characteristics are summarized in Table 2. The most common etiology of type III IF was SBS in 23 pts (37%). Seventeen patients were transplanted and required 24 procedures from evaluation to ITx and 43 after ITx.

Demographics	**Pediatric**	**Adult**	**Total**
Age			
Range	1-16	17-78	1-78
Mean +/- DS	5 *+/-4*	51*+/-19*	17*+/-24*
Sex			
Female/male	12/9	15/25	27/34
***CIF etiology**			

**SBS*	20	3	23
Intestinal Atresia	7	0	7
**CIPO*	0	6	6
Post-surgical	0	6	6
Intestinal Ischemia	0	5	5
Hirschsprung's	4	0	4
Gastroschisis	4	0	4
Volvulus	2	0	2
Megacolon	0	1	1
Omphalocele	0	1	1
Actinic enteritis	0	1	1
Trauma	0	1	1

Table 2. Patient's characteristics. Variables were divided in demographics, *CIF: Chronic Intestinal Failure, *SBS: Small bowel Syndrome, *CIPO: Chronic intestinal pseudo-obstruction.

When analyzing the procedures performed by IR, 166/173 (95.9%) were successful; the variables for the techniques used are described in Table 3. One hundred and forty-four of the implanted catheters were tunneled. Complications related to the procedures occurred in 18/173 (10.4%). Among these, 3 (1.73%) complications required catheter removal (Table 3 and Figure 2). Of note, 2 deaths were recorded and regarded as procedure-related. Up to the end of the follow-up period, 13/61 (21%) patients died due to non-procedure-related causes; 85% deaths occurred due to infections (fungemia, shock with an abdominal focus, pneumonia, meningitis) and the rest were related to cardiovascular events (heart failure, acute myocardial infarction).

Techniques used	**Number**	**%**
NCVA		
Subclavian or Jugular vein	39	22
Collateral subclavian or Jugular vein	39	22
Collateral retrosternal vein	31	18
Hepatic vein	20	12
Collateral femoral vein	15	9
Intercostal vein	13	8
**SVC - R.A*	5	3
Transhepatic IVC	4	2
Unsuccessful Treatment	7	4
Total	**173**	**100**
Type of Technique		
High Flow Collateral	49	28.3
Anterograde recannulation and/or direct approach	37	21.3
Alternative vein	31	17.9
Retrograde recannulation	24	13.8
Recannulation through collateral	17	9.8
Recannulation through azygous	8	4.6
Unsuccessful Treatment	7	4
Total	**173**	**100**
Guidance method		
Ultrasound	28	16
Radioscopy	127	73
Catheter / Anatomy	18	11
Total	**173**	**100**
Position of the catheter tip		
Collateral Vein	37	21
Inferior Vena cava	59	34
Right Atrium/ventricular	70	41
Procedure – related complications		
Thrombosis	7 (4 *peds)	4
Catheter malfunction	5 (2 peds)	3
Infection	3 (0 peds)	2
Hemothorax	1 (1 peds)	0.6
Pneumothorax	1 (0 peds)	0.6
Liver Hematoma	1 (0 peds)	0.6
		Total/Percentage

		18 (10%)

Table 3. Technical aspects and complications. *SVC- R. A: Superior Vena Cava- Right Atrium, *Peds: Pediatrics.

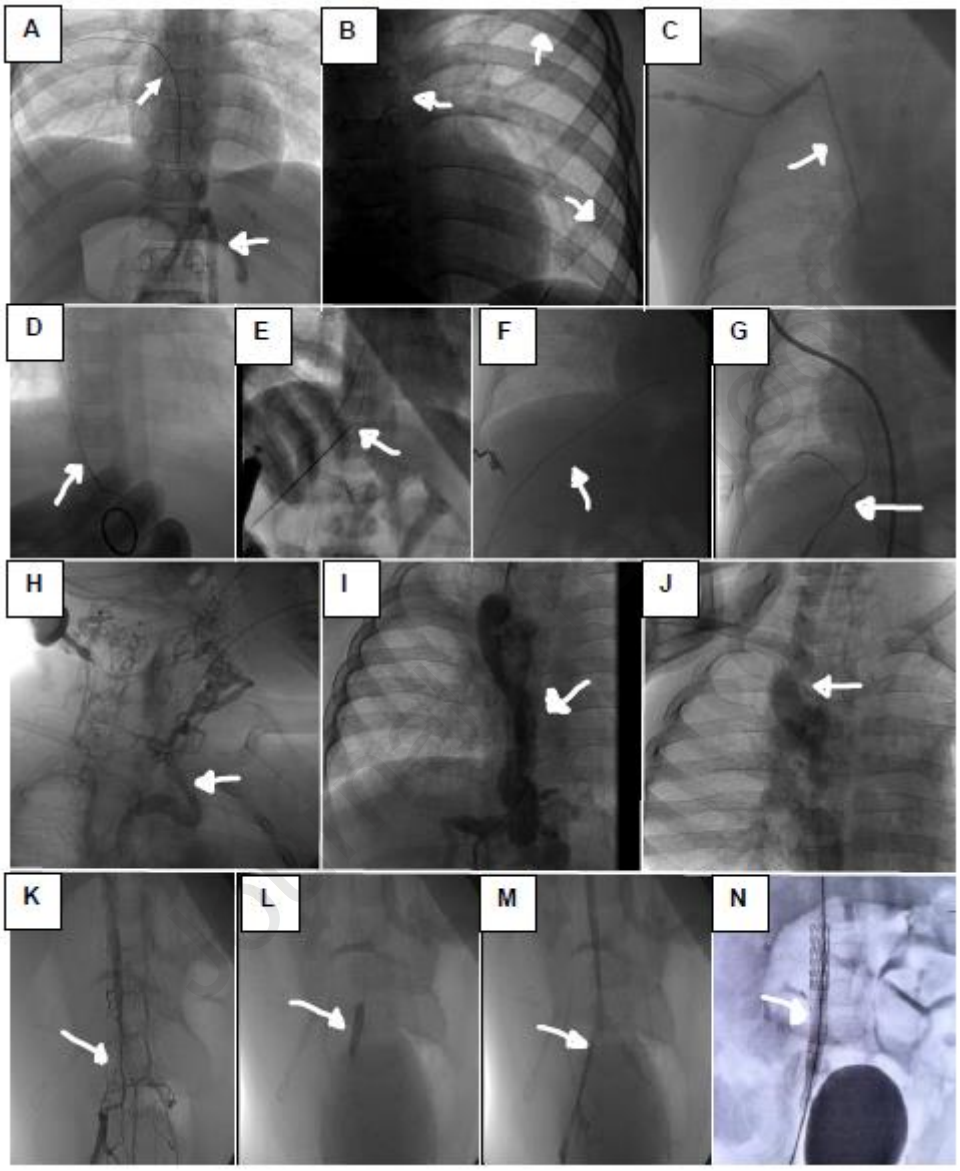

Figure 2. Interventional Radiology Techniques. ***A.*** Catheter implanted in Intercostal Vein with tip in high collateral vein, ***B.*** Catheter implanted in Intercostal vein with tip in right atrial, ***C.*** Catheter implanted in Right Innominate, ***D and E.*** Direct Approach of Inferior Vena Cava. ***F and***

G. Catheter Implanted Transhepatic, ***H, I and J.*** High Flow Collateral Vein. ***K.*** Right Iliac Vein occluded***, L.*** Balloon Angioplasty right Iliac Vein, ***M***. Angiography control, ***N.*** Implant of Stent.

On the other hand, 11 NCVA were implanted by the surgical team during the intestinal transplant engraftment in 10 recipients (Supplementary Figure 1).

Eight (72%) catheters were placed directly in the inferior vena cava (IVC), 2 (18%) in right gonadal vein, and 1 (9%) in the external iliac vein. One major complication (9%) related to a NCVA required laparotomy 45 days post-ITx showing that the tip of the catheter had migrated into the abdominal cavity, causing hemoperitoneum. Two (18%) catheters malfunctioned during the first week. One catheter was accidentally removed without causing any complication. The other 7 catheters were withdrawn 30 days after ITx surgery when were no longer needed.

SYSTEMATIC REVIEW

The systematic review was performed using a mesh search in PubMed including the terms listed under M&M resulting in a total of 337,542 publications, as of June 11th, 2020. From an initial result of 337,542 articles and following the PRISMA criteria, 64 full texts were evaluated; 14 of these (all case reports) were considered relevant (Figure 3).

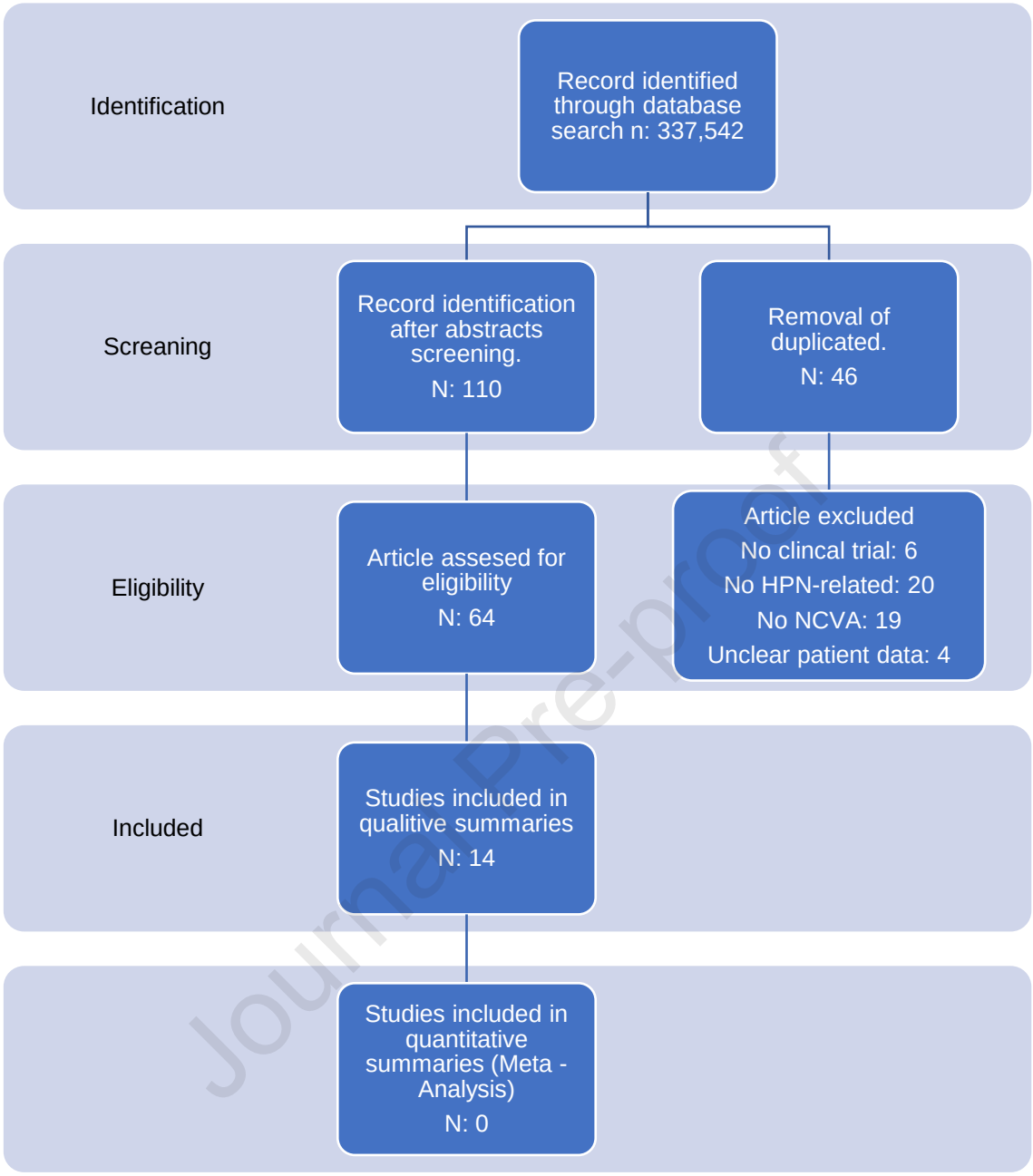

Figure 3. PRISMA Flow chart of study selection.

No randomized controlled trials or controlled non-randomized studies or interventions were identified. Extracted details of 14 studies are presented in Table 4 including the authors, date, number of patients, number of procedures, service or unit performing the procedure, patients´ age, etiology of type III IF, technique used, average patency rate, complications, successful ITx rate, and mortality [34-47]. The 14 studies included a total of 34 successful NCVA

procedures in 28 PN-patients with LCVA. The baseline characteristics of these patients are summarized in Table 4.

Author	Date	Operator	Pts	Procedure Number	Age Mean	IF causes	Boarding	Complication related	Catheter Permanence average
Apelgren KN	1981	Sx	1	1	55	SBS	Atrial	Haemothorax	60
Newman BM et al.	1983	Sx	2	6	1	SBS	Intercostal	Catheter Malfunction	50
Lammermeier D, et al.	1986	Sx	1	1	22	SBS	Intercostal		
Hemphill D,J et al.	1995	IR	2	2	44	Crohn's, Scleroderma	SVC		360
Chang MY, Morris JB	1997	Sx	1	1	70	Malabsorption, Scleroderma	Gonadal (ovarian)	Catheter Malfunction	
Patel NH	2000	IR	1	1	42	SBS	Translumbar		270
El Dannawi S, et al.	2004	Sx	1	2	17	Cystic Fibrosis, SBS	Azygous, Gonadal		2555
Rodriguez AF, et al.	2006	IR	6	6	2,3	SBS, Malabsorption, Volvulus	Atrial, Translumbar		
Mehta C, et al.	2006	IR	5	5	7	SBS, CIPO, Hirschhsprung's	SVC	Pneumothorax	135
Tang VC et al.	2007	IR	3	4	46	SBS	AVF		341
de Buys Roessingh AS	2007	IR-Sx	2	2	1	SBS	SVC		720
Sola JE, Thompson WR	2008	Sx	1	1	14	SBS – CIPO	Azygous		
Moise MA et al.	2009	IR	1	1	67	SBS	Azygous		
Detering SM. et al.	2011	Sx	1	1	11	Gastroschisis	Atrial		720
Subtotal			**28**	**34**					**564.4**
Perez Illidge, et al.	2021	IR	61	173	17	SBS, CIPO, Volvulus, Hirschsprung's, Intestinal Atresia, Post-surgical, Intestinal Ischemia, Gastroschisis, Megacolon, Omphalocele, Actinic enteritis	Transhepatic IVC, SVC – RA, Intercostal, Collateral femoral, Hepatic, retrosternal, Collateral subclavian or jugular, Subclavian or jugular.	Thrombosis, Pneumothorax Catheter Malfunction, Haemothorax, Liver Haematoma, Catheter-related infection.	738
		Sx	10	11			Inferior Vena Cava, Gonadal vein, External iliac vein.		26
Total			**99**	**218**					**543**

Table 4. Systematic Review with our single-center experience included. *IR: Interventional radiology, SX: Surgery, AVF: Arteriovenous Fistula, SVC: Superior Vena Cava, SBS: Small Bowel Syndrome, CIPO: Chronic Intestinal Pseudo-obstruction, m: male, f: female.

In 12 studies, the patients were predominantly male (13M/8F); however, in 2 studies, these data were not available. During follow-up, 7 patients (25%) underwent transplantation and 2 needed PN after ITx; however, the reason for PN requirement was not reported.

The 34 procedures described were reported as successfully performed, there is no data available regarding failure or complications related to the approach used. All the NCVAs described were done by puncturing a collateral vein. The cases reported were performed mostly by the IR team (58%), and the remaining (42%) were carried out by the surgical team.

The azygos/intercostals veins were the most widely used alternative site: (10) 29%, with direct puncture of the superior vena cava (SVC)/atrium: (10) 29%. Catheter patency range was 50–2555 days. Procedure-related complications were 4/34 (11.7%) (pneumothorax 1 (2.9%), Hemothorax 1 (2.9%), catheter malfunction 2 (5.8%). Reports mentioned that 1 pt died due to a procedure-related complications (2.9%), and 6 pts died from complications unrelated to the procedure (21%).

The degree of evidence revealed by the analysis of the publications selected is low because it is limited to case reports; no randomized control trials or meta-analyses were found as result of the literature search.

DISCUSSION

Gradual exhaustion of common venous accesses is a potential life-threatening outcome in patients under a chronic replacement therapy that depends on long-term central venous accesses [10]. One of the roles of a multidisciplinary team for type III IF is to prevent eventual occlusions and plan for alternative access in a systemic and objective manner to spare venous access options, minimizing associated complications and maximizing patient survival. These strategies should be considered in advance and ideally performed in centers of excellence [20].

Although some international guidelines and workshops recommend *how* and *where* the initial accesses should be placed and managed [48-49], repeatedly performed procedures involve a high risk of causing central venous thrombosis, leading to the loss the central venous access site. The ESPEN guidelines describe the vascular accesses most commonly used (Table 1), and suggest that the alternative accesses should be used when long-term PN complications occur in common sites [49-50]. However, due to the lack of recommendations in terms of the order of central veins to be used, the CVA workshop held at the 2015 ISBTS attempted to address this question; they proposed the term “rescue access” for the right and left common femoral veins, while hepatic veins, intercostal/lumbar veins, and IVC were named “non-conventional access” sites, and “last resource” access sites referred to those vessels with the potential to be used peri-operatively to facilitate transplant candidacy in these extreme situations. This includes surgical thoracotomy for direct SVC, azygous vein, or retrosternal venous collateral access [20].

As reported in the systematic review, since 1995, IR has become an essential part of the multidisciplinary teams for the management of type III IF. To the best our knowledge, the series here reported, is the largest single center experience described up to date.

Based on the experience acquired, the data analyzed has kept pace with the technical evolution developed by IR in recent years. Some outstanding contributions were the use of high flow collateral veins, not only for catheter placement, but also for the recannulation of occluded main vascular accesses (Supplementary Figure 2 and 3).

The repeated use of the technique over time, has changed the order of the NCVA preference in our team. From 2006 to 2010 the intercostal veins and transhepatic veins were the accesses used to manage LCVA; from 2011 to 2016 we experienced a transition period, using more and more collateral veins as an excellent option to implant catheters, providing a high flow vein, that grants access to a main vascular vein (like the SVC) allowing its recannulation (Table 5).

	From 2006 to 2010		From 2011 to 2015		From 2016 to 2019		*Total*
Subclavian or Jugular vein	4	11%	17	21%	18	36%	39
Collateral subclavian or Jugular vein	*5*	*14%*	22	27%	12	24%	39
Collateral retrosternal vein	*10*	*29%*	18	22%	3	6%	31
Supra-Hepatic vein	*4*	*11%*	10	12%	6	12%	20
Collateral femoral vein	*3*	*9%*	6	7%	6	12%	15
Intercostal vein	*7*	*20%*	4	5%	2	4%	13
*SVC - R.A**	*0*	*0%*	2	3%	3	6%	5
Transhepatic IVC	*2*	*6%*	2	3%	0	0%	4
Total	35		81		50		166

Table 5. Interventional Radiology technique evolution of NCVA by eras in our center.

At present, we recommend the use of high flow collaterals in cases of LCVA for the recannulation of the main supradiaphragmatic veins, finding this approach safer when compared to the use of a transhepatic access. In our experience, the use of the transhepatic access was associated with the death of 2 patients. Therefore, we agree with the recommendation made by the 2015 ISBTS CVA WS, advising that this access should only be used as a last resource [20].

Among the 14 articles included in the review, Tang et al, (see description 10 in Table 4) report patients that were management with an Arteriovenous Fistula (AVF). These patients were on hemodialysis for CKD, and already had this vascular access, which was used in the context of difficulty in making another

vascular access exclusive for PN. However, we understand that it is not a usual comorbid condition of patients with type III IF. Therefore, the use of AVF would not be an indication for patients without previous CKD. In our center, we do not have experience with the use this technique in IF patients but agree that it could be an option in a certain group of patients.

Comparatively, it has been reported in systematic reviews that catheters were placed by a surgical team in 42%, and by IR in 58%. In our series only 6% of the NCVA were implanted by surgery and 94% by IR since IR has been designated as the responsible for the NCVA placement as part of the multidisciplinary team approach.

According to the experience recorded in the observational studies, including our case series, a total 211/218 procedures performed in 99 patients were successful; NCVA-related complications reported are 10-11%, and the procedure-related mortality is about 1%. This shows that NCVA placement would be a safe procedure when performed by experienced teams. Nevertheless, other potential procedure related complications such as those associated to the fluoroscopy time and possible contrast-induced kidney injury need to be assessed. Longer follow-up time is needed to assess the long-term access patency. Studies with larger groups of patients would help to reach higher statistical power.

To date, evidence is modest provided that the published studies have not been randomized, controlled, or multicenter, but also the experience is limited due to

the small number of patients affected by this condition. For those patients that depend on permanent venous catheters for long term survival, the progressive LCVA sites should prompt a systematic approach to alternative sites and techniques to maximize patient survival and minimize complications. The comprehensive multidisciplinary teams should be familiar with the appropriate use of conventional and non-conventional types of venous access and their associated risks.

CONCLUSIONS

A structured protocol is needed for type III-IF patients requiring a long-term vascular access, in order to allow planning long term patency of available accesses; from conventional to non-conventional when needed. NCVAs should be placed by IR as part of a comprehensive multidisciplinary team, in centers of excellence.

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CONFLICT OF INTEREST

Authors do not have conflicts of interest to be disclosed.

AUTHOR CONTRIBUTIONS

Luis Perez Illidge: Data curation, Methodology and Writing.

Diego Ramisch: Data validation, Supervision and Manuscript Review.

León Valdivieso: Data curation, Supervision and Validation.

Carlos Guzman: Data curation, Supervision and Validation.

Diego Antoni: Data curation, Supervision and Validation.

Carolina Rumbo: Supervision, Manuscript review and editing.

Julio Trentadue: Data curation, Supervision and Validation.

Héctor Solar: Data curation, Supervision and Validation.

María Virginia Gentilini: Conceptualization, Methodology and Manuscript writing, review and editing.

Gabriel Gondolesi: Conceptualization, Methodology, Supervision, Manuscript review and editing.

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