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Echogenic large vein catheter for difficult intravenous access

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Limitations

This report is based on information available when the searches were made and does not contain data on subsequent developments or improvements of the evaluated technology. The observations made on effectiveness, safety or cost-effectiveness of the technology evaluated in the report are to be considered current but may change as more evidence becomes available if an update of the document is commissioned.

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Declaration of Conflict of Interest

The authors declare that they will not receive either benefits or harms from the publication of this report. None of the authors have or have held shares, consultancies or personal relationships with any of the producers of the devices assessed in this document.

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Name of the technology/procedure: **Echogenic large vein catheter for difficult intravenous access**

Target population

The echogenic large vein catheter assessed in the present Horizon Scanning report is intended for use in patients needing peripheral intravenous administration of fluids and medications but presenting difficult intravenous access (DIVA).

Description of the procedure and technology

Intravenous cannulation is a technique in which a catheter is placed inside a vein to provide venous access. Venous access allows sampling of blood, as well as administration of fluids, medications, parenteral nutrition, chemotherapy, and blood products [Scales K, 2008]. Venous catheters can be defined as central or peripheral. Central catheters end up in the thoracic portion of the vena cava or in the right atrium and can be inserted into the jugular or subclavian vein (centrally inserted central catheter, CICC) or into a peripheral vein in the arm, such as the cephalic vein, basilic vein or brachial vein (peripherally inserted central catheter, PICC) or into the femoral vein (femorally inserted central catheter, FICC). Peripheral catheters are inserted into a peripheral vein located in the arms, hands, legs and feet and their distal tip does not reach the vena cava or the right atrium.

Central venous cannulation must be performed with scrupulous attention to antisepsis and maximal sterile barriers to prevent catheter-related infections [RCN, 2016]. Chlorhexidine is commonly used as antiseptic and the operator should work wearing personal protection equipment [Bannon MP, 2011; European Policy Recommendations, 2013]. Typically, the equipment deemed necessary comprise the following items from the care bundle [Franklin BD, 2012]:

i) Hand hygiene facilities (hand washing facilities or alcohol gel);
ii) Personal protection (usually gloves alone but, when maximal sterile barriers are indicated, it may include apron, hat, mask, etc.);
iii) Skin preparation (e.g., 2% chlorhexidine in 70% isopropylalcohol);
iv) Peripheral venous cannula of appropriate size/gauge;
v) Specific peripheral intravenous cannula dressing.

Since peripheral catheters remain in place for a shorter time compared to central ones, the requirements in terms of antisepsis and sterile techniques may be less stringent but cannot exclude the use of an aseptic, no-touch technique. Moreover, while ultrasound may be necessary for proper orientation of the cannulating needle in some central catheterization sites (e.g., jugular vein), anatomic knowledge may be considered enough to perform a proper placement of a peripheral catheter.

The present assessment focuses on a new echogenic large vein catheter for DIVA. The device is indicated for cannulation of large veins (particularly the internal jugular vein) but is not proposed as a central catheter since its distal tip is not supposed to end up into the vena cava or in the right atrium. This new device claims higher echogenic properties, reduced procedure time for cannulation, and lower complications rate (e.g. catheter dislocation).

Clinical importance and burden of disease

Around 70-80% of hospitalised patients need a peripheral intravenous catheter [Van Loon F, 2016; Webster J, 2013; Rickard CM, 2012; Waitt C, 2004]. Further, for patients admitted to the Emergency Department, venous catheterisation is often either necessary or vital for immediate medical care, allowing intravenous administration of resuscitation fluids, drugs, and contrast agents if required for imaging. Depending on the clinical setting and patient's characteristics, peripheral intravenous access can, at times, prove to be difficult even for highly qualified medical or paramedical personnel [Sebbane M, 2013]. Peripheral Intravenous infusion is recommended when necessary therapies cannot be administered orally or are less effective if given by other routes.

The decision to obtain peripheral rather than central venous access depends upon clinical circumstances. In general, peripheral catheters are preferred when intravenous access is required for shorter periods, when direct access to the central circulation is unnecessary and when smaller gauge catheters suffice. Peripheral access is generally safer, easier to obtain and less painful than central access. There are few contraindications to the placement of peripheral venous catheters, and they are mainly related to problems with cannulation at a specific site. Successful peripheral intravenous cannulation can be influenced by various factors, such as palpable or visual absence of a vein, as well as diabetes mellitus, sickle cell disease, body habitus, vascular pathology, physician in training, burn injuries, intravenous drug abuse, fluid status, sex and age, clinician inexperience and clinician's judgment of poor peripheral venous access [Van Loon F, 2016, Sebbane M, 2013; Juvin P, 2003]. The sole absolute contraindication is when appropriate therapy can be provided by a less invasive route (e.g. orally).

DIVA is classically responsible for increased cannulation attempts, delaying patient management and increasing both adverse events and patient dissatisfaction. Multiple unsuccessful attempts to cannulate a peripheral vein are time consuming and are associated with additional risks such as nerve damage, paresthesia, hematoma and arterial puncture. Depending on the definition of DIVA adopted in each study, different estimates have been calculated, ranging from 10% to 24% in adults and up to 37% in children [Sabri A, 2013]. Estimates can approach 60% in complex patients [Armenteros-Yeguas V, 2017].

Products, manufacturers, distributors and approval

We identified a recently-patented catheter-over-needle device which is proposed for administration of fluids and medications in patients with DIVA. The device is marketed under the name JLB® and manufactured by DELTA MED, SpA. JLB® received the CE mark in March 2016 and is available in different lengths and calibres (60, 70, 80 mm and 14, 16, 17, 18 Gauge, respectively). The manufacturer stated that FDA approval has not been submitted.

According to the indications for use, the JLB® is to be used for ultrasound-guided access into large veins (particularly the internal jugular vein) on: i) patients with a depleted peripheral venous pool, and/or other medical conditions that do not allow conventional anatomical and peripheral venous cannulation, who need an intravenous infusion of drugs, electrolyte solutions, blood products, iso-osmolar parenteral nutrition; ii) patients in which it is assumed, for the clinical picture, a prolonged hospital stay and require parenteral therapy and frequent blood samples; iii) patients with hard to find conventional peripheral venous access who need to undergo surgery (pre and post-operative phase). It is possible, in case of need, to use the JLB® catheter already placed in the internal jugular vein as a guide for positioning a central venous catheter (CVC) with the Seldinger technique. The patients are usually over 18 years old with platelet levels over 100,000 and normal coagulation profile. JLB® is placed under ultrasound guidance and as a bedside procedure in large veins (internal jugular vein in particular).

Product name [Manufacturer]	Distributor	CE Mark	RDM	FDA
JLB® Internal Jugular Catheter [DELTA MED, SpA]	DELTA MED, SpA	☑	☑	☐

Roll out in Italy

The manufacturer stated that, since its introduction in March 2016, about 3,000 units of JLB® have been sold across 4 public hospitals in Emilia-Romagna region and marketing is limited to Italy. Within the *Flusso Consumi* (the Italian databank for monitoring the use of medical devices) of the NSIS (New Health Information System) we found that only three providers reported data on JLB® during 2017 (last accessed 21th June 2018).

☐ Pre-marketing	☐ On the market for 1-6 months	☐ On the market for 7-12 months
☑ On the market for more than 12 months	☐ Not identified	

Setting

The JLB® can be used in different hospital settings. The manufacturer's indications are not restricted to a specific setting and only recommend to create a sterile field by using chlorhexidine or povidone-iodine and follow and maintain an aseptic procedure.

☐ Home	☑ Hospital	☐Outpatient
☑ Accident and Emergency	☐ Other:	

Comparators

Comparators of the JLB® are all those devices intended for either central or peripheral venous cannulation: midline (20–25 cm), long peripheral access (6–12 cm) and short peripheral access (< 6 cm).

Effectiveness and safety

Systematic searches were performed on PubMed, Embase, and Cochrane Library during June 2018 and re-run during December 2018. We used a search strategy developed around combinations of relevant keywords (e.g. JLB® catheter, venous cannulation, midline). Relevant ongoing clinical trials were searched in the ClinicalTrials.gov database. Searches were started from 2015, year in which the identified device was

developed. Only studies on humans, published in English or Italian, reporting on the use of the specific device (JLB® by DELTA MED) were supposed to be included with no restrictions on study design.

Literature was selected according to the following criteria: i) population of patients with DIVA requiring intravenous administration of fluids and medications; ii) intravenous cannulation performed with the JLB® device; iii) comparators defined as intravenous cannulation performed with any standard device such as midline (20-25 cm), long peripheral access (6-12 cm) and short peripheral access (<6 cm). Relevant effectiveness outcomes were: procedural time; cannulation attempts; rate of success at first attempt; failure rate of intravenous cannulation. Relevant safety outcomes were: any adverse event (e.g., thrombophlebitis, extravasation of intravenous fluids, bruising, tissue haematoma, arterial puncture, pneumothorax, catheter infections); mean time of permanence in situ of the device; dislocation rate of the device; learning curve of the technique. When we first run the searches, we did not identify indexed studies. The only available record was a study published on the Italian Journal of Emergency Medicine, edited by Società Italiana della Medicina di Emergenza-Urgenza which is not indexed on PubMed. This is a cohort study whose complete results were not published yet and focused on the reporting of only 7 selected cases, considered to be the ones of greater clinical relevance [Brugioni L, 2017].

When we rerun searches in late November 2018, we identified the study presenting final results for the whole cohort [Brugioni L, 2018] and included it in the analysis. Brugioni et al. defined the study as multi-centre, observational, and prospective. Data were collected from June 2015 to February 2018. Acutely ill patients with DIVA and/or need for rapid infusion with age >18 years, admitted to three different Emergency Medicine Units, two Intensive Care Units, and one Gastroenterology ward were enrolled. In more than 2 years, 1,000 patients were enrolled in the study. The primary endpoint was to evaluate the feasibility and safety (detection of procedural and device-related complications) of achieving a peripheral venous access in acute ill patients using the JLB® device. The secondary endpoint was to assess the overall performance of the JLB® device, recording all major and minor complications and mean dwell time. Mean age of the cohort was 66.8 years and in total, 951 (95.1%) had the device placed in the internal jugular vein, 28 in the basilic or cephalic vein, 15 in the femoral vein, 5 in the axillary vein (infra-clavicular tract), and 1 in the external jugular vein. The procedure was performed by attending physicians or emergency medicine residents under ultrasound guidance. The JLB® was successfully inserted in 99.2% of patients. Mean procedure time (from disinfection to securing) was approximately 240 seconds. Mean number of attempts was 1.21. Early complications (<24 h) occurred in four patients, consisting in two soft tissue hematoma, one phlebitis, and one atrial tachyarrhythmia. No major complications (such as pneumothorax) were reported. Mean dwell time was 168 h (7 days); early occlusion/dislocation occurred in four cases (overall dislocation rate was 5/1,000 patients). The authors concluded that these preliminary data show that the use of JLB® appears to be safe, cost-effective, and rapid to place bedside.

Potential benefits to patients

Insertion of an intravenous catheter is required for most surgical procedures and in patients can cause anxiety and pain [Beck RM, 2011]. Particularly, obtaining peripheral intravenous access is not easy in all patients. This can be a stressful experience for an already anxious patient, especially when multiple attempts are necessary. Multiple unsuccessful attempts to cannulate a peripheral vein create a time-consuming situation and are associated with additional risks as nerve damage, paresthesia, hematoma, and arterial puncture [van Loon F, 2016]. Benefits for patients are the avoidance of the above problems. The absence of a needle/device in the arm also allows its movements and to undergo to fewer procedures that may be painful (e.g., blood sampling or easily switching from peripheral to central catheter).

☐ Mortality reduction or increased survival	☑Reduction of the morbidity	☑ Improved quality of life (patient/users)
☐ Improved patient monitoring	☐ Other	☐ Not identified

Cost of the technology/procedure

Specific systematic searches on PubMed, Embase, and Cochrane Library were also performed on June 2018 using a set of keywords to identify economic studies (e.g. economic evaluation; cost; cost-effectiveness), but no studies were found. Information on costs and reimbursement were gathered from manufacturer's questionnaire and from the *Flusso Consumi* databank. The price of the device resulted to be € 11.00 (VAT excluded).

☐ Increased costs compared to alternative treatments	☐ Increased costs due to increased demand	☐ Increased costs due to the required investments
☑ New costs	☐ Other:	☐Not identified

Potential structural and organisational impact

Structural impact

JLB® use does not have any structural impact. JLB® is a disposable device that is used in the same settings of its comparators and would require the same set of equipment (i.e. ultrasound unit) and disposable items to create and maintain a sterile field.

☐ Increase in requirement of instruments	☐ Always be used	☐ Can be used only under specific circumstances
☐ Decrease in requirement of instruments	☑ Other: no structural impact	☐ Not identified

Organisational impact

Use of JLB® involves only one professional, the clinician. However, different procedural guidelines across different settings and contexts may exist. The manufacturer stated that training is required to use JLB®, as provided by the Azienda Ospedaliera Universitaria (AOU) di Modena, by dr. Lucio Brugioni's team (dr. Brugioni is the inventor of the device). Both doctors and nurses receive training credits for that. The manufacturer reported that every user has been through a 5 hours training class before starting to use the device and that the first five procedures will be tutored by a skilled colleague. The manufacturer stated that no difference in success rate between the operators have been observed after the first procedures.

☐ Increase in the number of procedures	☐ Re-organisation required	☑ Training required for users
☐ Reduction in the number of procedures	☐ Other:	☐ Not identified

Conclusions

JLB® is meant for use in patients needing peripheral intravenous administration of fluids and medications but presenting DIVA. Benefits might be related to the avoidance of multiple unsuccessful attempts to cannulate which can lead to various associated risks. Until October 2018, JLB® was only available on the Italian market and sold in one region only (Emilia-Romagna). The device has no structural impact and requires a 5-hours training class to users. Only one observational study on this emerging technology has been identified [Brugioni at al 2018]. The primary investigator of the study is the inventor of the device. The study involved 1,000 patients from 2015 to 2018, enrolled at the hospital were the primary investigator works. Authors concluded that their preliminary data suggests that JLB® insertion is safe and rapid and, although data on costs are absent in the text, they claim the device's cost effectiveness. Study results are not definitive and an independent multicentre study would be needed to assess the clinical properties of the device.

Future prospects

The manufacturer of JLB® highlighted its commitment to the generation of evidence by publication of results of studies on indexed journals. Meanwhile, the manufacturer is considering furthering the diffusion of the device at national and international level through the launch of an improved version, the JLB® 3.0.

Evidence searches

Searches of the databases were carried out during June 2018 and updated during December 2018 using the following keywords to indicate:

- ***The technology of interest:*** JLB® catheter, venous cannulation, midline
- ***The pathology of reference:*** difficult intravenous access (DIVA)

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Glossary

AOU: *Azienda Ospedaliera Universitaria.*

CE: *Conformité Européene* - European Conformity.

CICC: centrally inserted central catheter.

CVC: central venous catheter

DIVA: difficult intravenous access.

FDA: Food and Drug Administration.

FICC: femorally inserted central catheter.

IJV: internal jugular vein

NSIS: *Nuovo Sistema Informativo Sanitario* - New Health Information System.

PICC: peripherally inserted central catheter.

RDM: Medical Device Repertory (http://www.salute.gov.it/dispositivi/paginainternasf.jsp?id=499&menu=repertorio).

SIMEU: Società Italiana della Medicina di Emergenza-Urgenza.

VAT: value added tax.