

# Epidural Catheter Design

## *History, Innovations, and Clinical Implications*

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### ABSTRACT

Epidural catheters have evolved during the past several decades, as clinicians and manufacturers have sought to influence the quality of analgesia and anesthesia and reduce the incidence of catheter-related complications. This evolution has allowed a transformation from single-shot to continuous-infusion techniques and resulted in easier passage into the epidural space, more extensive medication distribution, and ultimately, improved patient satisfaction. Particular catheter features, including the materials used, tip design, and orifice number and arrangement, have been associated with specific outcomes and provide direction for future development. (**ANESTHESIOLOGY 2014; 121:9-17**)

**F**ROM its origins as a modified ureteral catheter, the epidural catheter has evolved into versions made with silk, rubber, plastic, and coiled stainless steel. These changes resulted from a growing recognition that particular design elements could potentially influence catheter performance. This article reviews the history of epidural catheter design, focusing on how modifications in the materials used, tip design, and orifice number and arrangement may have affected analgesic and anesthetic outcomes, and provides a summary of the comparative studies that evaluate the clinical performance of distinct epidural catheter design features.

### History

The most consistent entry into the epidural space for the administration of anesthesia occurred at the turn of the 20th century when the French physicians Jean A. Sicard, M.D. (1872–1929; Professor, Department of Pathology, Necker Hospital; Laboratory of Professors Raymond and Brissaud, Salpêtrière Hospital, Paris, France) and Fernand Cathelin, M.D. (1873–1945; Department of Surgery, University of Paris Faculty of Medicine, Paris, France) independently introduced single-shot epidural blocks *via* the caudal approach for neurologic and genitourinary procedures, respectively (table 1).<sup>1</sup> Within a few years, German physicians Walter Stoeckel, M.D. (1871–1961; Honorary Professor, Department of Gynecology, Berlin Charité, Berlin, Germany) and Arthur Lāwen, M.D. (1876–1958; Professor, Department of Surgery, University of Leipzig Faculty of Medicine, Leipzig, Germany) applied this technique for obstetric deliveries and surgical procedures to the perineum.<sup>2</sup> During the 1920s, Gaston Labat, M.D.<sup>3</sup> (1876–1934; Laureate of the Faculty of Sciences, University of Montpellier, Montpellier, France;

Laureate of the Faculty of Medicine, University of Paris Faculty of Medicine, Paris, France), Barnet E. Bonar, M.D.<sup>4</sup> (1894–1937; Department of Pediatrics, Rush Medical College, Chicago, Illinois; Member of the American Academy of Pediatrics, Salt Lake City, Utah), and William R. Meeker, M.D. (1889–1955; Head of Section on Anesthesia, Division of Surgery, Mayo Clinic, Rochester, Minnesota), among others, also advocated the caudal approach for epidural anesthesia.

The Spanish surgeon Fidel Pagés Miravé, M.D. (1886–1923; Medical Commandant, Department of Surgery, Emergency Military Hospital of Madrid, Madrid, Spain) reported the first single-shot thoracolumbar epidural anesthesia in 1921.<sup>5</sup> Within a decade, the Italian surgeon Achille M. Dogliotti, M.D. (1897–1966; Professor, Department of Clinical Surgery, University of Turin, Turin, Italy) described a reproducible loss-of-resistance technique to identify the epidural space.<sup>6</sup> Contemporaneously, the Argentine surgeon Alberto Gutiérrez, M.D. (1892–1945; Chief of Surgery, Hospital Español, Buenos Aires, Argentina; Extraordinary Professor, University of Buenos Aires School of Medicine, Buenos Aires, Argentina) described the “sign of the drop” method for identification of the space.<sup>7</sup> Charles B. Odom, M.D.<sup>8</sup> (1909–1988; Director of Surgical Services, Charity Hospital, New Orleans, Louisiana), John R. Harger, M.D., F.A.C.S.<sup>9</sup> (1876–1956; Professor, Department of Surgery, University of Illinois; Attending Surgeon, Cook County Hospital, Chicago, Illinois), and John Abajian, Jr., M.D.<sup>10</sup> (1921–1996; Captain, Medical Corps, Army of the United States; Professor, Chief of the Division of Anesthesiology, Department of Surgery, University of Vermont College of Medicine, Burlington, Vermont) popularized the single-shot

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**Table 1.** Pioneers of Continuous Epidural Techniques

Timeline	Pioneer(s)	Novel Development
1901	Jean Sicard; Fernand Cathelin	Independently introduced single-shot caudal blocks
1910	Arthur Låwen; Walter Stoeckel	Advocated caudal blocks for pelvic and obstetric surgeries
1921	Fidel Pagés Miravé	Introduced single-shot thoracolumbar approach to epidural analgesia
1923	Gaston Labat; Barnet Bonar; William Meeker	Advocated caudal approach for epidural anesthesia
1930	Alberto Gutiérrez	Described the “hanging drop” method for identification of the epidural space
1931	Achille Dogliotti	Described loss-of-resistance technique to identify the epidural space
1931	Eugene Aburel	Introduced a continuous catheter technique to block the lumboaortic plexus during early stage of labor
1930	Charles Odom; John Harger; John Abajian	Early practitioners of epidural anesthesia in North America
1938	Peter Graffagnino; Louis Seyler	Applied single-shot epidural anesthesia in obstetrics
1940	William Lemmon	Introduced a continuous spinal technique <i>via</i> a malleable needle
1941	Samuel Manalan	Used catheter technique for labor analgesia
1942	Robert Hingson; Waldo Edwards; James Southworth	Modified the malleable Lemmon needle; pioneered an approach to continuous caudal analgesia in obstetrics
1942	Charles Adams; John Lundy; Thomas Seldon	Advocated continuous caudal technique for peripartum analgesia
1944	Edward Tuohy	Introduced the ureteral catheter for continuous spinal anesthesia; modified the Huber needle for epidural use
1944	James Southworth; Robert Hingson	Attempted a modified continuous lumbar epidural technique
1947	Manuel Martinez Curbelo	Introduced continuous lumbar epidural anesthesia with ureteral catheters

thoracolumbar epidural technique in the United States. In 1938, clinicians at the Louisiana State University Medical Center reported the first application of this technique to the obstetric population.<sup>11</sup>

A number of innovations attempted to prolong single-shot epidural procedures. In 1931, Eugen B. Aburel, M.D. (1899–1975; Professor, Department of Obstetrics and Gynecology, University of Medicine and Pharmacy, Iasi, Romania) introduced a continuous lumboaortic plexus block with a silk ureteral catheter to alleviate labor pain.<sup>12</sup> Clinicians at the Mayo Clinic had previously reported using ureteral catheters for alternative purposes, including for the treatment of hydrocephalus.<sup>13</sup> Aburel’s combination of a continuous lumboaortic block for the first stage of labor and a single-shot caudal for the second stage yielded unreliable results and was abandoned as more promising continuous techniques evolved.<sup>14</sup>

Robert A. Hingson, M.D., Sc.D. (1913–1996; Chief of Anesthesiology, U.S. Marine Hospital, Staten Island, New York; Director of Anesthesia, Lying-In Hospital, Philadelphia, Pennsylvania; Professor, Department of Anesthesiology, Western Reserve University School of Medicine, Cleveland, Ohio) and Waldo B. Edwards, M.D. (1905–1981; Chief of Obstetrics, U.S. Marine Hospital, Stapleton, Staten Island, New York), both affiliated with the United States Public Health Service during the Second World War, pioneered an approach to continuous caudal analgesia for the obstetric population in 1942 with the use of a modified Lemmon needle. William T. Lemmon, M.D. (1896–1974; Junior Faculty Member, Department of Anatomy, Jefferson Medical College and Hospital, Philadelphia, Pennsylvania)

had originally developed the malleable spinal needle, made of German silver, to provide continuous spinal anesthesia.<sup>15</sup> Hingson and Edwards<sup>16</sup> described inserting a 19-gauge malleable stainless steel needle into the sacral canal and attaching the hub to a Luer-Lock syringe *via* a four-foot length of rubber tubing. The authors reported occasional complications, such as needle breakage, and warned of the theoretical possibility of undetected needle migration into the subarachnoid space.

Edward B. Tuohy, M.D., M.S. (1908–1959; Major, Medical Corps, Army of the United States; Chief of Anesthesia and Operative Section, Percy Jones General Hospital, Battle Creek, Michigan; Consultant, Mayo Clinic, Rochester, Minnesota; Professor, Department of Anesthesiology, Georgetown University Medical Center, Washington, D.C.) introduced the ureteral catheter for continuous spinal anesthesia in the early 1940s, thereby eliminating some of the drawbacks associated with the malleable needle. In his early works, he described threading a graduated, round-tipped nylon ureteral catheter through a 15-gauge Barker needle at the level of the lower lumbar vertebrae and connecting a rubber adapter or, alternatively, a 22-gauge needle to the free end for dosing.<sup>17</sup> Tuohy<sup>18</sup> cautioned that catheters should be properly sterilized and, in the absence of any obvious breaks or cracks, reused not more than 10 times.

Several other investigators introduced the catheter as an alternative to an indwelling needle for continuous caudal anesthesia. Samuel A. Manalan, M.D. (1912–1990; Department of Obstetrics and Gynecology, Indiana University School of Medicine, Indianapolis, Indiana)

presented the catheter technique in a preliminary report in 1940.<sup>19</sup> He described threading a number 4-French\* ureteral catheter through a 14-gauge needle into the sacral canal.<sup>20</sup> Nylon ureteral catheters, which were more easily sterilized, replaced silk catheters during the course of his pilot study due to a case of meningitis that was attributed to the latter.

R. Charles Adams, M.D. (1906–1956; Faculty Member, Head of Section on Anesthesia and Intravenous Therapy, Mayo Clinic, Rochester, Minnesota), John S. Lundy, M.D. (1894–1973; Professor, Head of Section on Anesthesia, Mayo Clinic, Rochester, Minnesota), and Thomas H. Seldon, M.D. (1905–1991; Faculty Member, Mayo Clinic, Rochester, Minnesota) also contributed to the advancement of the epidural catheter technique in the early 1940s.<sup>21</sup> Their continuous caudal technique for peripartum analgesia involved threading a woven silk or nylon number 5-French ureteral catheter through a 13-gauge Love-Barker needle at the level of the third sacral foramen. Catheter curling, tearing, cracking, and improper sterilization were among the complications associated with this technique.

With the collaboration of the surgeon James L. Southworth, M.D. (1913–1970; Assistant Surgeon, U.S. Marine Hospital, Stapleton, Staten Island, New York), Hingson<sup>22</sup> modified the continuous technique again in 1944, this time introducing a blunt-tipped silk ureteral catheter into the lumbar epidural space *via* a large Barker needle. However, a high incidence of paresthesias, inadequate analgesia, unilateral blockade, and intravascular cannulation forced the collaborators to devise a new approach. Familiar with the work by Francis R. Irving, M.D.<sup>23</sup> (1896–1959; Clinical Professor, Department of Obstetrics and Gynecology, Syracuse University College of Medicine, Syracuse, New York) in the field of continuous caudal anesthesia, Southworth and Hingson attempted placing the Barker needle over an 18-gauge hubless Irving needle to facilitate catheter insertion, but abandoned this approach in favor of a continuous epidural technique with a malleable 19-gauge spinal needle inserted at the T12-L1 interspace. Innovations in spinal and epidural catheterization, however, soon superseded this technique.

Shortly after visiting the Mayo Clinic in 1946, Cuban anesthesiologist Manuel Martinez Curbelo, M.D. (1906–1962; Department of Anesthesiology, Hospital Municipal de la Habana, Havana, Cuba) adapted Tuohy's continuous subarachnoid technique for the epidural space, using 16-gauge

Tuohy needles and small, graduated number 3.5-French ureteral catheters that curved as they exited the needle.<sup>12</sup> He advocated continuous epidural anesthesia for a broad range of surgeries, from the neck to the lower extremity. Charles E. Flowers, Jr., M.D. (1920–1999; Instructor, Department of Obstetrics and Gynecology, Johns Hopkins University and Hospital, Baltimore, Maryland) and Louis M. Hellman, M.D. (1908–1990; Professor, Department of Obstetrics and Gynecology, State University of New York College of Medicine; Director of Obstetrics and Gynecology, Kings County Hospital, Brooklyn, New York), both at Johns Hopkins University at the time, collaborated with Hingson to apply Martinez Curbelo's technique to the obstetric population. They threaded plastic tubing *in lieu* of a ureteral catheter through a blunt-tipped 16-gauge Tuohy needle at the level of the second lumbar interspace to provide analgesia or anesthesia for vaginal or cesarean delivery.<sup>24</sup>

In the late 1940s, John G. Cleland, M.D., C.M., M.Sc., F.A.C.S. (1898–1980; Clinical Instructor, Department of Obstetrics and Gynecology, University of Oregon Medical School, Portland, Oregon) devised an alternative method of pain relief in the obstetric population with a dual continuous lumbar and caudal epidural technique.<sup>25</sup> With the goal of selectively blocking pain at different stages of labor, he placed one number 3.5-French ureteral x-ray catheter between the second and third lumbar vertebrae and a second "soft-nosed" number 3.5-French catheter in the caudal canal. The caudal catheter, autoclaved in the straightened position to prevent kinking or curling, was placed at the same time as the lumbar catheter but was activated only when the parturient reached the second stage of labor.

By the second half of the 20th century, the practice of epidural analgesia had gained popularity in North America. In 1951, Oral B. Crawford, Jr., M.D. (1921–2008; Department of Anesthesiology, St. John's Hospital, Springfield, Missouri) and colleagues reported more than 600 cases of thoracic epidural anesthesia.<sup>26</sup> Similarly, in 1953, F. Paul Ansbro, M.D. (1899–1977; Assistant Clinical Professor, Department of Anesthesiology, St. Catherine's and Adelphi Hospitals, Brooklyn, New York) and colleagues reported success with more than 1000 single-shot and continuous epidural anesthetics for a variety of surgeries, including gastrectomies, thyroidectomies, and kidney and chest surgeries.<sup>27</sup>

Obstetric anesthesia also gained momentum as epidural techniques became more widespread. John J. Bonica, M.D. (1917–1994; Professor and Chairman, Department of Anesthesiology, University of Washington School of Medicine, Seattle, Washington) organized one of the first 24-h labor anesthesia wards in the late 1940s,<sup>28</sup> and published his classic textbook, *Principles and Practice of Obstetric Analgesia and Anesthesia*, 2 decades later.<sup>29</sup> Philip R. Bromage, M.B., B.S., F.F.A.R.C.S., F.R.C.P. (1920–2013; Professor and Chairman, Department of Anesthesia, McGill University, Montreal, Canada; Professor, Departments of Anesthesiology and

\* The French scale (or gauge) system was devised by Joseph-Frédéric-Benoît Charrière, a 19th-century Parisian maker of surgical instruments, who defined the "diameter times 3" relationship, meaning the external diameter of a catheter in millimeters multiplied by three results in the French gauge.<sup>20</sup> As an example, a catheter with a 3-mm external diameter is a French size of 9. An increasing French size corresponds to a larger external diameter. The measurement is most commonly abbreviated as Fr, but Ga, FR, F, CH, or Ch (for its inventor) are also used.

Obstetrics and Gynecology, Duke University Medical Center, Durham, North Carolina), who advanced the concept of providing regional analgesia as a complement to general anesthesia, introduced his classic text *Epidural Analgesia* in 1978.<sup>30</sup> Broader commercial availability of epidural catheters, the first report of intrathecal opioid efficacy, and the formation of pain services also occurred in the 1970s. The acceptance and proliferation of analgesic and anesthetic applications for the epidural catheter prompted further innovations in catheter materials and designs.

### Catheter Design Innovations and Clinical Implications

During the past few decades, a number of innovations in the design and manufacture of epidural catheters have been made, including changes in the materials used, tip design, and orifice location and number. Comparative studies that evaluate the clinical performance of these distinct epidural catheter design features have been performed; however, a number of factors should be acknowledged when interpreting their results.

First, most of the catheters discussed were approved under the 510(k) program of the Medical Device Amendment to the Federal Food, Drug, and Cosmetic (FD&C) Act.<sup>†</sup> Enacted in 1976, this program allows a device that exhibits “substantial equivalence to a legally marketed device” to be marketed without independent demonstrations of safety and effectiveness. As a consequence, robust, blinded assessments of the altered epidural catheter design feature likely did not occur during the approval process, with claims regarding the efficacy of a design modification being the result of internal, manufacturer-conducted investigations. Second, many of the published investigations were nonrandomized, open-labeled trials performed at a time when industry support and relevant conflicts of interest were not routinely disclosed. It is possible that bias in conducting the research, interpreting the findings, or publishing the results may have occurred. Finally, some of the studies evaluating epidural catheter modifications were small in number and did not disclose whether anatomic approaches to the epidural space (*e.g.*, midline *vs.* paramedian), methods used to identify the epidural space (*e.g.*, loss-of-resistance, hanging drop, and many more), and the experience of persons placing the technique were standardized; these may have confounded the results. With an appreciation of these potential study limitations, the epidural catheter design features may be reviewed.

#### Innovations in Catheter Materials

The materials used in the production of catheters directly affect the length at which coiling occurs,<sup>31</sup> deformability to force,<sup>32</sup> intrinsic bending stiffness, and tensile strength.

These properties, in turn, may influence clinical outcomes, such as analgesic spread, paresthesias, intravascular cannulation, kinking, breakage, and migration. During the past several decades, materials have evolved to improve the flexibility and reduce the complications associated with catheters.

Ureteral catheters used initially for cerebrospinal fluid drainage and then adapted for continuous spinal and epidural techniques were made of various materials. In the 1930s, woven natural silk catheters with gum elastic interior walls were widely available.<sup>33</sup> However, during the Second World War when silk became scarce, ureteral catheters of nylon, a synthetic polymer, became more common. Early prototypes were flexible at body temperature, required cold sterilization, and were equipped with red rubber adapters to connect with syringes. By 1942, autoclavable silk and nylon catheters impregnated with a woven gum coating for improved longevity and elasticity replaced previously imported products. Lacquered nylon number 3.5- or 4-French ureteral catheters used for epidural techniques were available in radiopaque and nonradiopaque versions, with or without centimeter gradations.

Advances in the plastics industry eventually led to the development of catheters that better withstood the sterilization process. Polyethylene, a widely available plastic, is easily deformed during the autoclaving process and at body temperature. Polyvinylchloride catheters, available in bulk in the 1960s, proved more resistant to kinking and easier to place than polyethylene versions; however, the intrinsic stiffness of polyvinylchloride may have contributed to a higher incidence of tissue trauma, intravascular cannulation, and dural punctures. Polyvinylchloride tubing was cut, marked with centimeter gradations, and sterilized by autoclaving by individual anesthesia providers.<sup>34</sup>

Nylon, a polyamide, largely replaced polyvinylchloride because of its improved tissue inertness, transparency, and tensile strength. The high melting point of nylon confers an ability to withstand the sterilization process and retain its shape at body temperature. Nylon is sufficiently flexible to stretch rather than buckle or break, yet rigid enough to thread easily. Many currently available catheters are nylon blends.

Teflon<sup>®</sup> (E.I. du Pont de Nemours and Company, Wilmington, DE), a brand name for polytetrafluoroethylene, emerged in the manufacture of epidural catheters in the 1970s. Polytetrafluoroethylene has an extremely low coefficient of friction that facilitates catheter placement, a high melting point, which minimizes thermolability, and greater tensile strength than polyvinylchloride or polyethylene. However, the stiffness of Teflon<sup>®</sup> catheters may contribute to displacement from the epidural space, kinking or fracture, venous cannulation, and paresthesias. A comparative study of central venous catheters indicated that Teflon<sup>®</sup> catheters were up to 10 times stiffer than silicone elastomer, polyvinylchloride, and polyurethane catheters; reducing the diameter of Teflon<sup>®</sup> catheters to limit their stiffness results in sizes that are not clinically viable.<sup>35</sup>

<sup>†</sup> Available at: <http://www.fda.gov/medicaldevices/deviceregulation-andguidance/guidancedocuments/ucm282958.htm>. Accessed January 13, 2014.



Wire-reinforced catheters, manufactured in the United States by Teleflex® (Durham, NC; formerly Arrow International, Reading, PA), B. Braun Medical Inc. (Bethlehem, PA), and Epimed (Johnstown, NY) represent the most recent technological advance in epidural catheter design. The inner wire coil is designed to provide sufficient columnar strength for insertion, lumen patency, and kink resistance,<sup>36</sup> and is surrounded by either a polyurethane or nylon-blend catheter, depending on the manufacturer. The technique by which the outer coating is attached to the inner stainless steel spring also varies with the manufacturer; some use a “tipping” process in which the proximal and distal ends alone are melded together, whereas others secure the entire length of the coil to the surrounding material in a proprietary extrusion process. Wire-reinforced catheters are all designed with fewer coils in the distal tip, which reportedly confers greater flexibility to minimize paresthesias and perforations of the dura and epidural vessels,<sup>31</sup> and with distal and proximal flashback windows for visualization of cerebrospinal fluid or blood. Adult versions are 19-gauge in diameter (designed for use with a 17-gauge epidural needle) and are available in either single end-hole (*i.e.*, open-tipped) or closed-tipped, multiorifice versions, with or without a stylet. The catheter bodies are radiopaque; however, one manufacturer considers its catheter “magnetic-resonance-conditional” based on nonclinical testing, which allows for use under specific conditions (*i.e.*, a static magnetic field of 3-Tesla or less, a maximum spatial gradient magnetic field of 720-Gauss/centimeter or less, and a transmit/receive radio frequency head coil).

### Clinical Implications of Catheter Materials

The materials used in the manufacture of catheters have been observed to have some effect on clinical performance, including ease of placement and removal and the incidence

of paresthesias and intravascular cannulations. Many commercially available catheters are made of nylon blends with intermediate bending stiffness, which facilitates threading and increases the likelihood of successful insertion.<sup>37</sup> Other nylon and polyurethane catheters have an inner stainless steel wire coil to impart rigidity, with fewer coils in the distal tip to impart flexibility; how this more flexible tip influences threading ease or failure has not been fully investigated.

The rigidity of catheter materials also seems to influence the incidence of paresthesias. Soft-tipped, flexible catheters are believed to result in fewer paresthesias because they curl up or change course as they brush against nerve roots or other obstacles in the epidural space.<sup>38</sup> Catheter materials that soften at body temperature, such as polyurethane, have been observed to reduce the paresthesia rate;<sup>39</sup> however, this is unlikely to be important during the initial placement due to the time required for temperature equilibration. A number of studies demonstrate a significantly lower incidence of paresthesias with springwound polyurethane *versus* non-wire-reinforced catheters (table 2). In a study of 222 attempts at epidural placement in 200 parturients randomized to receive continuous epidural analgesia, Banwell *et al.*<sup>40</sup> reported an incidence of paresthesias of 3 of 112 with a single end-hole springwound polyurethane catheter compared with 39 of 110 with a blunt-tipped, multiorifice nylon catheter ( $P < 0.0001$ ); the catheters were likely 19- and 20-gauge, respectively (actual gauge not provided), based on the products being produced by the companies.

Slight modifications in the materials of non-wire-reinforced catheters by a single manufacturer seem to have a negligible impact on the incidence of paresthesias. In a prospective cohort-controlled study of 188 patients receiving either a 20-gauge polyamide or a 20-gauge polyurethane-polyamide

**Table 2.** The Incidence of Paresthesias and Intravascular Cannulation with Various Epidural Catheters

Study	Catheter	Paresthesia	Intravascular Cannulation	Comment
Banwell <i>et al.</i> <sup>40</sup>	Arrow FlexTip Plus® (open-tip, polyurethane)	2.7%	0%	Prospective, randomized, unblinded study (n = 200 parturients). Epidural catheter gauge not provided.
	Concord/Portex® (blunt-tip, nylon with three lateral holes)	35.5%	10%	
Bouman <i>et al.</i> <sup>39</sup>	20-gauge B Braun Perifix Standard (polyamide)	21.3%	8.9%	Prospective, open, cohort-controlled study (n = 188 patients). The incidence of paresthesias increased to 37.8% (standard) and 32.6% (new), respectively, on direct questioning by the observer. The study was inadequately powered to detect a difference in intravascular cannulation between the two groups.
	20-gauge B Braun Perifix New (combined polyamide-polyurethane)	16.7%	3.2%	
Terasako <i>et al.</i> <sup>42</sup>	19-gauge Arrow FlexTip Plus® (open-tip, polyurethane)	NA	0.67%	Prospective, randomized, study (n = 300 parturients).
	19-gauge Hakkō catheter (open-tip, polyethylene)	NA	5.3%	

Arrow FlexTip Plus® (Teleflex®, Durham, NC, formerly Arrow International, Reading, PA); Concord/Portex® (Smiths Medical, St. Paul, MN). NA = not assessed.

catheter, Bouman *et al.*<sup>39</sup> reported no significant difference between the incidence of paresthesias between the two catheters (21.3 *vs.* 16.7%;  $P = 0.42$ ). Overall, evidence suggests that paresthesias occur less frequently with springwound polyurethane catheters compared with non-wire-reinforced nylon and polyamide-polyurethane blend catheters. Studies comparing springwound catheters from different manufacturers, each of which has a different material surrounding the inner wire coil, are currently lacking.

Catheter materials can also influence the incidence of intravascular cannulation. Collectively, softer, single end-hole catheters and, specifically, flexible wire-reinforced polyurethane catheters have been observed to have a lower incidence of intravascular cannulation compared with conventional catheters (table 3).<sup>41</sup> Terasako *et al.*<sup>42</sup> randomized 300 patients to receive either a 19-gauge wire-reinforced polyurethane open-tipped or a 19-gauge polyethylene open-tipped catheter and found a statistically significant lower incidence of intravascular cannulation in the former group (1 of 150 *vs.* 8 of 150). In a 1998 study, Banwell *et al.*<sup>40</sup> randomized 200 parturients requesting continuous epidural analgesia to receive either a nylon catheter or a wire-reinforced polyurethane catheter and reported 11 of 110 episodes of venous cannulation in the former group and no cases in the latter ( $P = 0.0007$ ). As in the case of paresthesias, slight changes in the materials of non-wire-reinforced catheters by a single manufacturer seem to have a negligible impact on the incidence of epidural vein cannulation.

Catheter breakage also seems to be related to the mechanical properties of materials used. However, comparative studies on the tensile strength of wire-reinforced *versus* non-wire-reinforced catheters have resulted in conflicting findings. Nishio *et al.*<sup>43</sup> undertook a comparative study on the tensile strength of seven different 19-gauge epidural catheters under traction from both a stainless steel hemostat and a rubber-sleeved hemostat. When stretched with a rubber-sleeved hemostat, catheters made of polyurethane

demonstrated the greatest tensile strength. One nylon catheter demonstrated slightly less tensile strength, with another nylon catheter demonstrating significantly less. The materials with the lowest tensile strength were polyethylene and Teflon<sup>®</sup>. Interestingly, all catheters demonstrated less tensile strength under traction from a steel hemostat, with polyurethane and polyethylene catheters exhibiting the least. These findings suggest that the use of a stainless steel hemostat or similar instruments should not be used to extract epidural catheters that are difficult to remove.

Ateş *et al.*<sup>44</sup> reported similar high tensile strength with polyurethane catheters compared with clear nylon and radiopaque nylon catheters in their blinded, controlled study on intact and traumatized catheters by three different manufacturers. Specifically, nontraumatized polyurethane catheters stretched more than 300% of their original length without breaking, whereas all other catheter specimens broke before the elongation limit of the tensile testing machine was reached. Of note, some clinicians have characterized the elasticity associated with the wire-reinforced polyurethane catheter as a disadvantage; the distal tip may remain immobile and allow the proximal portion to stretch until breaking.<sup>45</sup> In the event of entrapment of wire-reinforced catheters, some clinicians have indicated that removal may be facilitated by placing the patient in the lateral decubitus position or in the original insertion position, reattempting removal in 30 to 60 min, or applying gentle, continuous traction. Alternatively, threading a stylet into the catheter or injecting saline into a soft springwound catheter has also been observed to assist in extracting a “trapped” catheter.<sup>46</sup>

Other investigators have observed diminished tensile strength of wire-reinforced *versus* non-wire-reinforced catheters and of springwound polyurethane catheters exposed to higher temperatures. Asai *et al.*<sup>47</sup> performed an *ex vivo* study on the degree of stretching, the force required to snap, and the site of breakage of four 19-gauge catheters made by different manufacturers. The springwound polyurethane

**Table 3.** The Incidence of Complications in Studies Comparing Uniport and Multiport Epidural Catheters

Study	Catheter	Paresthesia	Intravascular Cannulation	Inadequate Analgesia	Comment
Michael <i>et al.</i> <sup>58</sup>	Nylon uniport Portex <sup>®</sup>	12.2%	5.7%	32.7%	Prospective, randomized, single-blind study (n = 802 patients).
	Nylon multiport Portex <sup>®</sup>	8.5%	10.5%	13.7%	
Collier and Gatt <sup>59</sup>	Nylon uniport Portex <sup>®</sup>	28%	4.0%	32%	Prospective, randomized, single-blind study (n = 200 parturients). Terminated early (n = 102) due to high incidence of inadequate analgesia in uniport group.
	Nylon multiport Portex <sup>®</sup>	17.3%	7.7%	11.5%	
D'Angelo <i>et al.</i> <sup>60</sup>	Nylon uniport Braun	41%	7.0%	31.8%	Prospective, randomized, unblinded study (n = 500 parturients).
	Nylon multiport Braun	42%	6.5%	21.2%	
Jaime <i>et al.</i> <sup>61</sup>	Springwound uniport Arrow <sup>®</sup>	6%	1.1%	3.3%	Prospective, quality assurance study (n = 1,352 parturients uniport; n = 1,260 parturients multiport).
	Nylon multiport Portex <sup>®</sup>	11.2%	5.7%	4.4%	

Arrow<sup>®</sup> (Teleflex<sup>®</sup>, Durham, NC, formerly Arrow International, Reading, PA); Concord/Portex<sup>®</sup> (Smiths Medical, St. Paul, MN).

catheter stretched significantly more ( $P < 0.001$ ) and snapped at a significantly lower weight ( $P < 0.01$ ) than the three conventional non-wire-reinforced nylon catheters. In comparing the tensile strength of similarly designed 19- and 20-gauge springwound polyurethane catheters at 22° and 37°C (“room” vs. “body” temperature), Tsui and Finucane<sup>48</sup> found a slightly reduced tensile strength of all catheter samples at the higher temperature, with no significant differences between the two catheters at the two temperatures studied. The authors found that the mean fracture force required to break either of these catheters at 37°C was 1.98 and 1.99 kg; this was greater than both the previously reported mean force required to remove an epidural catheter from a patient (0.17 to 0.32 kg) and the maximum withdrawal force (1.17 kg). They concluded that these catheters were therefore unlikely to fracture under normal clinical circumstances.

Catheter occlusion, kinking, and/or knotting may be associated with a number of factors, including the port configuration, depth of insertion, method of catheter fixation to the skin, and, in the case of wire-reinforced catheters, the method of attaching the inner wire coil to the surrounding coating; however, one implicated cause has been the materials used to manufacture catheters. In the late 1990s, slight alterations in the manufacturing materials used in Portex® (Smiths Medical, St. Paul, MN) catheters were associated with a globally reported high incidence of occluded catheters.<sup>49</sup> Reinforced catheters, such as the BD Ribflex catheter (Becton, Dickinson and Company, Franklin Lakes, NJ) with internal longitudinal ribs throughout its length, introduced in the 1990s, and, more recently, wire-reinforced catheters have been observed to confer kink resistance, better flow characteristics, and improved patency when compared with non-wire-reinforced versions.<sup>50</sup> Knotting of the epidural catheter is a rare complication (with an estimated incidence of 0.0015% and rate of one in 20,000 to 30,000)<sup>51</sup> that can lead to reinstrumentation, replacement, difficult removal, and breakage. Limiting the amount of catheter threaded into the epidural space may reduce the risk of this complication. Reports regarding neurologic sequelae from retained portions of broken catheters have been uncommon, suggesting that surgical removal is likely not warranted in the asymptomatic patient.<sup>52</sup>

### **Innovations and Clinical Implications in Catheter Tip Design**

In 1962, J. Alfred Lee, M.R.C.S., L.R.C.P., M.M.S.A., F.F.A.R.C.S., D.A. (1906–1989; Senior Consultant Anaesthetist, Southend University Hospital, Westcliff-on-Sea, Essex, United Kingdom) introduced a closed-tipped, flexible nylon catheter with a lateral opening 1 cm from the tip, designed to facilitate insertion and minimize tissue trauma.<sup>53</sup> A catheter with two lateral orifices for a more reliable spread of local anesthetics soon followed, but was prone to kinking. Basil S. Skinner, M.D. (1917–1993; Chairman of the

Department of Anaesthesia, Queen Elizabeth Hospital, Barbados, West Indies) subsequently developed an open-ended, blunt-tip catheter with a lateral hole 3 mm from the tip.<sup>34</sup> Catheters with two lateral orifices on opposing sides, one at 5 mm and a second at 12 mm from the closed tip, and later, with three orifices followed.<sup>54</sup>

Limited data preclude a robust assessment of whether the position and number of catheter ports significantly affect the spread of analgesia, incidence of paresthesias and intravascular cannulation, and potential for a multicompartimental blockade. Some studies suggest that single-orifice, open-end catheters reliably detect intravascular and subarachnoid placements and limit infusions to one anatomic site. Multi-orifice, closed-tipped catheters, when compared with single end-hole catheters, have been observed to result in improved injectate distribution,<sup>55</sup> greater likelihood that aspiration of cerebrospinal fluid or blood can occur from one of the orifices in the event of a misplaced catheter, and diminished likelihood of orifice blockage by a clot or adjacent tissue. Furthermore, the blunt-tipped multiport catheter is potentially less traumatic, reducing the likelihood of intravascular cannulation. However, a multiport catheter can result in a multicompartiment block<sup>56</sup> and preferential efflux from a single or all ports based on the rate and pressure of injectate delivery.<sup>57</sup> As a result of the preferential efflux, rapid manual boluses are likely to recruit all ports, including the distal port, for injectate delivery; theoretically, this may be a reason why a distal port that has migrated into a vascular, subarachnoid, or subdural location may go unnoticed during a slower, continuous infusion.

A number of studies have compared single- and multi-orifice catheters to determine the optimal number and positioning of ports (table 3). A single-blind, randomized study in 802 parturients found a significantly higher incidence of inadequate analgesia with open-end, uniport (32.7%) versus closed-end, multiport (13.7%) nylon catheters ( $P < 0.001$ ).<sup>58</sup> Although not reaching statistical significance, intravascular cannulation occurred more frequently in the closed-end group (10.5 vs. 5.7%), but open-end catheters were reportedly more difficult to place. In a randomized, single-blind study of smooth-tipped, open-end uniport versus closed-end, multiport (8, 12, 16 mm from tip) nylon catheters, Collier and Gatt<sup>59</sup> planned to enroll 200 obstetric patients but were forced to abandon the study after 102 patients had been assessed due to the incidence of unsatisfactory block in the uniport (32%, 16 of 50 patients) versus multiport (11.5%, 6 of 52 patients) group ( $P = 0.016$ ). Ultimately, all patients with unsatisfactory analgesia in the uniport group developed an adequate block after catheter adjustments and redosing. The overall rate of intravascular cannulation was low in both the uniport (4%) and multiport (8%) groups. Pain or paresthesia on insertion did not reach statistical significance between the terminal (28%) and lateral orifice (17%) catheters.

In a randomized, nonblinded study on an 18-gauge multiport (three lateral ports) versus a uniport (single distal hole)

nylon epidural catheter in 487 laboring patients, D'Angelo *et al.*<sup>60</sup> demonstrated that the multiport catheter had less inadequate analgesia (21.2 *vs.* 31.8%, respectively,  $P < 0.05$ ) and reduced need for catheter manipulation (44.2 *vs.* 31.4%, respectively,  $P < 0.05$ ). The incidence of catheter replacement, intravascular cannulation, and paresthesia on insertion was similar in both groups. One uniport catheter was inadvertently placed intrathecally.

To date, few published studies have compared traditional multiport catheters and newer wire-reinforced catheters in terms of analgesic efficacy or the incidence of complications. In a prospective quality assurance study, Jaime *et al.*<sup>61</sup> compared clinical complications in 2,612 obstetric patients who received epidural analgesia with either a 20-gauge closed-tipped, multiport (three lateral ports) nylon catheter or a 19-gauge open-end, uniport springwound polyurethane catheter. The incidence of unsatisfactory block was similar in both the groups (nylon catheter 4.4%, 55 of 1,260 patients *versus* springwound polyurethane catheter 3.3%, 45 of 1,352 patients), but the incidence of paresthesias, venous cannulation, and reinsertion related to venipuncture was significantly higher in the patients who received the non-wire-reinforced nylon catheters.

Until recently, a comparative study on flexible, wire-reinforced nylon or polyurethane catheters that differed in the number of holes at the tip had not been undertaken. However, a prospective, single-blind, randomized, controlled trial conducted in 2009 by Spiegel *et al.*<sup>62</sup> investigated the success of labor analgesia, the number of episodes of breakthrough pain requiring supplemental medicine, and the occurrence of complications, such as paresthesias and intravascular and intrathecal catheters, in 493 parturients who received either a single end-hole wire-reinforced polyurethane catheter or a multiorifice wire-reinforced nylon catheter. The authors found no statistically significant difference in outcomes between the two groups and postulated that the flexibility afforded by the wire coil may eliminate any of the potential advantages of the multiport design.

## Conclusion

Epidural catheter material and tip design seem to affect the ease of catheter placement and removal, the extent and quality of analgesia and anesthesia, and associated complications. However, much of the existing data are limited to a few randomized controlled studies, observational findings, and case reports. Additional studies with multivariate analysis are needed to explain more fully the relation between epidural catheter design modifications and performance or complications and to guide future catheter developments that may enhance patient safety and satisfaction.

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