

# Coaxial Drainage Versus Standard Chest Tube After Pulmonary Lobectomy: A Randomized Controlled Study

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## Research article

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# Abstract

**Objectives:** Chest tubes are routinely inserted after thoracic surgery procedures in different size and numbers. The aim of this study is to assess the efficacy of Smart Drain Coaxial drainage compared with two standard chest tubes in patients undergoing thoracotomy for pulmonary lobectomy.

**Methods:** Ninety-eight patients (57 males and 41 females, mean age  $68.3 \pm 7.4$  years) with lung cancer undergoing open pulmonary lobectomy were randomized in two groups: 50 received one upper 28-Fr and one lower 32-Fr standard chest tube (ST group) and 48 received one 28-Fr Smart Drain Coaxial tube (**SDC** group). Hospitalization, quantity of fluid output, air leaks, radiograph findings, pain control and costs were assessed.

**Results:** We performed 33 right upper lobectomies (17 ST, 16 **SDC**), 25 right lower (15 ST, 10 **SDC**), 20 left upper (8 ST, 12 **SDC**) and 19 left lower (10 ST, 9 **SDC**). **SDC** group showed shorter hospitalization (7.3 vs 6.1 days, **p=0.02**), lower pain in postoperative day-1 (**p=0.02**) and a lower use of analgesic drugs (**p=0.04**). Pleural effusion drainage was lower in **SDC** group in the first postoperative day ( $464 \pm 143$  ml vs  $408 \pm 141$  ml, **p=0.04**) and regarding the average of the first three days ( $374 \pm 96$  ml vs  $324 \pm 95$  ml, **p=0.01**). No difference in terms of fluid retention, residual pleural space, subcutaneous emphysema and complications after chest tubes removal was found.

**Conclusions:** Smart Drain Coaxial chest tube seems a **feasible** option after thoracotomy for pulmonary lobectomy. The **SDC** group showed a **shorter** hospitalization and a **decreased** analgesic drugs use and, thus, a reduction of costs.

## Introduction

Chest tubes are routinely inserted after major thoracic surgery procedures and vary largely in literature in terms of size, numbers and timing of removal. Most of the surgeons prefer to leave two chest drainage after thoracotomy for major pulmonary resections. Even though we have learned a lot from single chest tube drainage after minimally invasive lobectomy, there is still some restriction and reserve in using a single tube when the chest is approached through thoracotomy. It has been already reported that single pleural drain after pulmonary lobectomy is safe and effective (1 - 4) but none of these studies is definitive.

The Smart Drain Coaxial (SDC) chest tube (Redax. Modena, Italy), is built with an internal lumen with distal bores for air evacuation and four external fluted channels for fluid drainage (Fig.1); this conformation allows to drain air and effusions along the entire length of the tube. This device has been already evaluated in a recent retrospective study (5), with promising results.

In this regard, the aim of this study is to compare the use of two standard tubes (STs) with one SDC after thoracotomy for pulmonary lobectomy. The primary endpoint aims at verifying the efficacy of SDC in terms of fluid and air drainage evaluating the daily quantity of fluids collected and the presence of

postoperative pneumothorax or pleural effusion at radiological imaging; the secondary endpoint was to assess incidence of complications after chest tubes removal, postoperative pain, hospital stay and costs compared to STs.

## Patients And Methods

### Study population

The study was approved by institutional Ethics Committee of Policlinico Umberto I, Department PARIDE STEFANINI, informed consent was taken from all the patients and trial registered in ClinicalTrials.gov (ID NCT04877925). Between February 2017 and April 2018, ninety-eight consecutive patients (57 M and 41 F, mean age  $68.3 \pm 7.4$  years, median  $69.0 \pm 10.8$ ) undergoing pulmonary lobectomy for lung cancer through lateral thoracotomy were included in the trial. Sample size has been calculated according to international literature on this topic and considering a confidence level at 95% and margin of error 5%. Inclusion criteria were: age more than 18 years; patient with lung cancer scheduled for open pulmonary lobectomy after a multidisciplinary team discussion. All patients were adequately informed and they have signed a consensus to participate. Exclusion criteria were: middle lobectomy, extended resections, minimally invasive lobectomies, previous ipsilateral thoracic surgery, induction chemo- and/or radiotherapy and patients who did not give consent to participate.

Patients were randomized into two groups using the block randomization procedure: 50 patients received one upper 28 Fr and one lower 32 Fr standard chest tube (ST group) and 48 patients received one 28 Fr SDC tube (SDC group). The result of randomization was communicated to the surgeon at the end of the surgical procedure, just before tube placement.

### Clinical data

Clinical and surgical variables were prospectively collected including: age, gender, comorbidity, smoking history, type of surgery, intensive care unit (ICU) length of stay (days), stage, chest drainage daily fluid output (mL), daily air leakage (+/-), postoperative pain score assessed by a visual analogue scale (VAS), administration of analgesic drugs, steroids and diuretics, therapy at discharge, radiologic evaluation of pleural effusion, pneumothorax or subcutaneous emphysema, postoperative hospital stay and incidence of complications. Regarding the fluid output, the daily effusion and the total collection entered the analysis with the aim to compare any difference between groups in day-by-day output and in larger periods of time (first-3 days and overall hospital stay)

Postoperatively, chest X-ray (CXR) was routinely performed on the first and third postoperative day (POD). A -20 cmH<sub>2</sub>O suction was applied at the end of the operation and maintained until the removal of chest tubes. Chest tubes were removed when pleural effusion was less than 300 mL/24h in absence of air leaks for at least 24 hours. CXR was also performed 24h after removal of the drainage.

The quantity of pleural effusion was evaluated with CXR using a 4-grade scale, as reported by Mammarrappallil and colleagues (6), at the first and third POD, and after tube removal: 0 - normal costophrenic angles; 1 - fluid meniscus below the hemidiaphragms; 2 - fluid meniscus at the level of hemidiaphragms; 3 - fluid opacity obscures the hemidiaphragms.

## Statistical analysis

Statistical analysis was performed using SPSS v.17 (SPSS Inc., Chicago, IL, USA). Categorical data are presented as number and percentages; continuous data as mean  $\pm$  standard deviation (SD) and median  $\pm$  inter-quartile range (IQR). Fisher exact test was used to compare categorical data. Student's t test and Mann Whitney U test were used to compare normally distributed and non-normally distributed continuous data after Shapiro-Wilk test respectively. A p-value  $\leq$  0.05 was considered statistically significant.

## Results

Baseline characteristics and operative data are reported in Table 1. No statistical differences were found between the two groups in terms of age, sex, smoking history, comorbidity, side of operation and staging. All patients but two had a peridural catheter for postoperative pain management with infusion of ropivacaine 240 mcg and morphine 3 mg for 24h at 2 mL/h. The remaining two patients, received 2 mL/h intravenous infusion of Sufentanyl 4 mcg pro kg for the first 24 h. In addition, as standard management, paracetamol 1 g was intravenously infused three times per day (BASE group). Supplementary administration of analgesic drugs (i.v. ketorolac or morphine's bolus) was recorded (PLUS group).

Right upper lobectomy was performed in 34 (34.7 %) patients, right lower lobectomy in 25 (25.2 %), left upper lobectomy in 20 (20.4%) and left lower lobectomy in 19 (19.4 %). All patients received systematic mediastinal lymph node dissection. Seventy-one patients had pulmonary adenocarcinoma (72.4%), 11 squamous cell carcinomas (11.2%), 4 atypical carcinoids (4.1%), 2 small cell lung cancers (2%), 5 (5.1%) other primary lung cancers and 5 pulmonary metastases from previous malignances (5.1%). In all the patients, the regular lobectomy plus systematic lymphadenectomy was performed without intraoperative complications, extension of the procedure and showed no significant anatomical variances.

Postoperative data are reported in Table 2. The mean POD at discharge was  $6.7 \pm 2.6$  days, with a median postoperative hospital stay of 6 days (from 4 to 20 days). The SDC group showed a significantly lower postoperative hospitalization (mean  $6.1 \pm 2.0$  days vs  $7.3 \pm 3.1$ ; median  $6.0 \pm 2.0$  vs  $6.5 \pm 2.8$  days;  $p=0.02$ ). Overall, this was significantly longer in patients who presented at least one postoperative complication ( $p=0.01$ ). The most frequent postoperative complication was persistent air leakage (PALs, 9.2%), followed by pneumonia (4.1%) and atrial fibrillation (2%). There was no difference between ST and SDC groups in incidence of postoperative complications ( $p=0.67$ ). Thirty-six patients (36,7%) were scheduled for preventive ICU stay after surgery (22 ST and 14 SDC;  $p=0.13$ ). The mean ICU stay was  $1.17 \pm 0.51$  days, without any difference between the SDC and ST groups ( $p=0.30$ ). The mean chest tube maintainance was  $5.0 \pm 2.0$  days (median  $5.0 \pm 1.0$ ) with SDC group showing a shorter chest drain use (mean  $4.7 \pm 1.9$  days vs  $5.3 \pm 2.2$  days; median  $4.0 \pm 2.0$  days vs  $5.0 \pm 2.0$ ;  $p =0.04$ ).

During the first POD, air leaks were observed in 15 (30%) and 12 (25%) patients in ST and SDC group ( $p=0.58$ ) respectively. Air leak decreased down to 40% and 58% respectively after three days. PALs, defined as persistence of air leaks for more than 5 days, were recorded in 9 (9.2%) patients without any difference between the two groups (5 ST, 4 SDC;  $p=0.76$ ). The mean hospital stay in presence of PALs was  $10.4 \pm 3.4$  days (median  $9.0 \pm 1.0$ ) versus  $6.3 \pm 2.3$  (median  $6.0 \pm 1.0$ ) days in patients without PALs ( $p=0.007$ ). PALs were treated in 2 (22.2 %) patients with blood patch and conservatively in the remaining.

The SDC group showed a lower total fluid drainage (median  $1150.0 \pm 651.5$  mL vs  $1477.5 \pm 762.5$  mL;  $p$ -value= $0.07$ ). This difference was statistically significant in POD 1 (median  $400.0 \pm 200.0$  ml vs  $450.0 \pm 193.8$  ml,  $p=0.04$ ) and as a mean of first three PODs (median  $325.0 \pm 137.5$  ml vs  $362.5 \pm 96.7$  ml,  $p=0.01$ ). Fluid drainage was also assessed at CXR using a 4-grade scale; no difference was observed between groups on POD 1 (ST 1.3 vs SDC 1.1;  $p=0.34$ ), POD3 (ST 1.0 vs SDC 0.9;  $p=0.76$ ) and after tube removal (ST 1.3 vs SDC 1.2;  $p=0.65$ ). The pleural fluid retention rate, defined as percentage of patients with grade 2 or 3 at CXR evaluation, showed no difference between the two groups in POD 1 (ST 32% vs SDC 18.8%;  $p=0.13$ ), POD 3 (ST 26% vs SDC 27%;  $p=0.90$ ) and after tube removal (ST 40% vs SDC 37.5 %;  $p=0.80$ ).

The mean postoperative pain, measured with the VAS in first, third and fifth POD, was  $4.1 \pm 1.3$  for ST group and  $3.7 \pm 1.3$  for SDC group, without significant difference ( $p=0.11$ ). However, ST group significantly complained higher pain in POD1 ( $5.5 \pm 1.9$  vs  $4.6 \pm 1.7$ ;  $p=0.02$ ). Thirty-nine patients (39.8%) required the administration of supplementary analgesic drugs and 25 of them (64.1%) were of ST group ( $p=0.03$ ).

Complications after chest tube removal occurred in 22 patients (22,4%) (ST 13 vs SDC 9) without statistical significance between the two groups ( $p=0.47$ ). The most frequent complication was pneumothorax (14.3%) followed by pleural effusion (5.1%), hydropneumothorax (2%) and subcutaneous emphysema (1%). No one of these occurrences required additional procedures.

Moreover, we have investigated the economic impact including the costs of each tube, hospitalization and the amount of supplemental drugs administration for pain control. As reported in Table 3, we have observed a significant difference between the two groups with the SDC group showing lower costs ( $p=0.04$ ).

## Discussion

Historically, textbooks recommended the use of two chest tubes after mayor pulmonary resections: one placed inferiorly to drain fluids and one towards the apex to facilitate lung expansion (7). A 1999 survey showed that more than 90% of thoracic surgeons in the United Kingdom used two drains after anatomical or non-anatomical pulmonary resections (8).

In the last decades, many studies reported that a single chest tube could be adequate (9). Four randomized clinical trials (1 – 4) compared the use of one chest tube with the standard two chest tubes in patients undergoing lobectomy and/or bilobectomy. All the studies concluded that one chest tube was

“non-inferior” compared to two chest tubes, without statistically significant differences in terms of hospital stay, pleural drain capability and post-removal complications. Furthermore, Alex et al (1) and Okur et al. (3) observed a significantly decrease in postoperative pain and Gomez-Caro et al. (2) reported a reduction of analgesic drugs administration.

A recent meta-analysis (10) showed that the use of a single chest drain is more effective than two to reduce postoperative pain and facilitate patients to adhere to postoperative physiotherapy, resulting in a shorter hospitalization. Despite that, some institutions still prefer to insert two tubes after thoracotomy to optimize fluid and air drainage (11, 12). In fact, there is still reserve in using a single chest tube after open thoracic procedure because of the possibility of avoiding suboptimal pleural space management. Concerns are still debated because tube clotting is observed in up to 5.8% of the patients with one chest tube (5, 13), along with other complications such as loculated pleural effusion and inefficient fluid drainage of the costophrenic angle. At the same time, none of clinical studies have shown the superiority of two standard chest tubes over a single chest tube after pulmonary lobectomy. In this regard, we have assumed that double chest tubes are still the most representative standard of practice worldwide.

Recently, a new flexible coaxial drain was developed to combine the benefits of two separate chest drains with the proven advantages of one chest tube. It is made of biocompatible silicone and is composed by four external fluted channels for fluids drainage and an internal section which allows separate air evacuation from appropriate distal bores. Compared with STs, the draining surface area provided by SDC is considerably wider and resistant to clot occlusion. Furthermore, Guerrero et al. showed that SDC provides a satisfactory air evacuation even in patients with significant air leaks (14).

In 2017, Rena et al. (5) retrospectively compared 52 patients treated with SDC with 104 patients with standard two chest tubes after open or VATS lobectomy: SDC resulted “non-inferior” in fluid and air evacuation, hospital stay and rate of postoperative complications. However, one of the limitations of that study was the retrospective nature and the absence of randomization.

This is the first randomized clinical trial comparing the use of two standard tubes with one SDC. SDC resulted as an effective option after pulmonary lobectomy. Regarding fluid drainage, the SDC group showed a lower fluid evacuation compared to ST group, in particular during the first three PODs. However, at CXR there was no difference between the two groups in terms of pleural effusion, suggesting that one SDC tube provides sufficient cleaning of the chest cavity. Indeed, the draining surface provided by SDC is wider than both superior and inferior STs. Thus, the higher fluid evacuation provided by two ST, estimated at approximately 50 mL per day, might be the effect of the pleural reaction to the presence of a double big bore catheters.

Concerning air aspiration, SDC appears “non-inferior” to STs. The air leaks rate is similar between the groups, as well as the rate of PALs. SDC provides adequate air evacuation even in presence of high flux air leaks. The rate of fixed pleural space (15), defined as incomplete re-expansion of the lung after resection in absence of air leaks, is similar in the two groups and it seems more related to patients’ characteristics than to inadequate air evacuation.

In our series, SDC group showed a significantly shorter hospitalization. This could be explained with the tendency of patients to promptly adhere to mobilization and physiotherapy. In fact, even if the mean postoperative pain showed no significant differences between the groups, the SDC group showed a significantly lower pain in POD1. This topic is crucial in the era of enhanced recovery after surgery (ERAS). Late mobilization has been proven to be an independent factor correlated to delayed discharge and increased morbidity (16). Furthermore, in our series, ST patients more often required additional analgesic drugs suggesting an inadequate pain control, despite no differences in VAS score. However, the comparison between a double chest tube versus a single chest tube technique might be quite obviously associated to a better outcome after a single chest tube. This assessment could lead to a future research interest for comparing single SDC versus a single standard chest tube.

Finally, although costs of single SDC is remarkably higher compared to STs, the shorter hospital stay and lower analgesic drugs administration drop the total costs.

This study presents some limitations: although it is a randomized study, the number of patients is relatively small and different surgeons performed the surgical procedures. Finally, this is a single center experience and larger multicenter studies are required to confirm our results.

## **Conclusion**

In conclusion, our results suggest that SDC might be a feasible option after open pulmonary lobectomy with similar results in terms of fluids drain capability, air suction and post removal complications compared to two standard chest tubes. Furthermore, SDC group showed less analgesic drugs requirement, lower postoperative pain in POD1 and a shorter hospital stay and, thus, a reduction of costs.

## **Abbreviations**

Smart Drain Coaxial (SDC)

Standard tubes (ST)

Intensive care unit (ICU)

Visual analogue scale (VAS)

Chest X-ray (CXR)

Postoperative day (POD)

Standard deviation (SD)

Prolonged air leaks (PALs)

Enhanced recovery after surgery (ERAS).

# Declarations

- **Ethics Approval and consent to participate**

The study was approved by the ethic committee of Policlinico Umberto I, University of Rome (nr.2/2020). Consent has been obtained from all patients.

- **Consent for Publication**

Consent for publication has been obtained from all patients

- **Availability of supporting data**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

- **Competing interests**

The authors declare that they have no competing interests.

- **Funding**

Not applicable

- **Authors contributions**

Massimiliano Bassi: Conception and design, Data analysis and interpretation, manuscript writing, final approval of manuscript; Emilia Mottola: Data analysis and interpretation, manuscript writing, final approval of manuscript; Sara Mantovani: Provision of study materials, Collection and assembly data, final approval of manuscript; Davide Amore: Administrative support, Data analysis and interpretation, final approval of manuscript; Andreina Pagini: Administrative support, Data analysis and interpretation, final approval of manuscript; Daniele Diso: Administrative support, Data analysis and interpretation, final approval of manuscript; Camilla Poggi: Provision of study materials, Collection and assembly data, final approval of manuscript; Jacopo Vannucci: Provision of study materials, Collection and assembly data, final approval of manuscript; Tiziano De Giacomo: Conception and design, Data analysis and interpretation, final approval of manuscript; Erino Angelo Rendina: Conception and design, Data analysis and interpretation, manuscript writing, final approval of manuscript; Federico Venuta: Conception and design, Data analysis and interpretation, manuscript writing, final approval of manuscript; Marco Anile: Conception and design, Data analysis and interpretation, Collection and assembly data manuscript writing, final approval of manuscript.

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## Tables

**Tab 1.** Baseline characteristics and operative data

	<b>Overall</b>	<b>Standard</b>	<b>Coaxial</b>	<b>p-value</b>
<b>n</b>	98	50	48	
<b>Age</b>	68.3 ± 7.4	69.0 ± 7.1	67.6 ± 7.8	<b>0.21</b>
<b>Male</b>	57 (58.2 %)	28 (56 %)	29 (60 %)	<b>0.69</b>
<b>Lobe</b>				<b>0.54</b>
<b>Left lower lobe</b>	19 (19.4 %)	10 (10.2 %)	9 (9.2 %)	
<b>Left upper lobe</b>	20 (20.4 %)	8 (8.2 %)	12 (12.2 %)	
<b>Right lower lobe</b>	25 (25.5 %)	15 (15.3 %)	10 (10.2 %)	
<b>Right upper lobe</b>	34 (34.7 %)	17 (17.3 %)	17 (17.3 %)	
<b>Histology</b>				<b>0.09</b>
<b>Adenocarcinoma</b>	71 (72.5 %)	34 (34.7 %)	37 (37.8 %)	
<b>Squamous cell cancer</b>	11 (11.2 %)	9 (9.2 %)	2 (2.0 %)	
<b>Others</b>	16 (16.3 %)	7 (7.1 %)	9 (9.2 %)	

Data are n(%) or mean ± standard deviation

**Tab 2.** Post-operative characteristics.

	Overall	Standard	Coaxial	p-value
<b>Length of stay (days)</b>	6.7 ± 2.6 <b>6.0 ± 1.0</b>	7.3 ± 3.1 <b>6.5 ± 2.8</b>	6.1 ± 2.0 <b>6.0 ± 2.0</b>	<b>0.02</b>
<b>Tube stay (days)</b>	5.0 ± 2.0 <b>5.0 ± 1.0</b>	5.3 ± 2.2 <b>5.0 ± 2.0</b>	4.7 ± 1.9 <b>4.0 ± 2.0</b>	<b>0.04</b>
<b>Postoperative complications</b>				
Overall	18 (18.4 %)	10 (10.2 %)	8 (8.2 %)	0.67
Persistent air leaks	9 (9.2 %)	5 (5.1 %)	4 (4.0%)	0.76
Sputum retention	4 (4.0 %)	2 (2.0 %)	2 (2.0 %)	
Atrial Fibrillation	2 (2.0 %)	2 (2.0 %)	0 (0.0 %)	
Others	3 (3.1 %)	1 (1.0 %)	2 (2.0 %)	
<b>ICU admission</b>	36 (100%) (36.7%)	22 (22.4 %)	14 (14.3%)	0.13
<b>ICU stay (days)</b>	1.2 ± 0.7	1.2 ± 0.6	1.1 ± 0.3	0.30
<b>Air leaks detection</b>				
POD 1	27 (27.5%)	15 (15.3 %)	12 (12.2 %)	0.58
POD 3	14 (14.3 %)	9 (9.2 %)	5 (5.1 %)	
<b>Amount of drainage (mL)</b>				
Overall		1624.9 ± 718.5	1363.5 ± 692.2	0.07
		<b>1477,5 ± 762,5</b>	<b>1150.0 ± 651.5</b>	
POD 1		464.4 ± 143.0 <b>450.0 ± 193.8</b>	407.9 ± 141.4 <b>400.0 ± 200.0</b>	<b>0.04</b>
POD ≤ 3		374.2 ± 96.1 <b>362.5 ± 96.7</b>	323.9 ± 94.5 <b>325.0 ± 137.5</b>	<b>0.01</b>
<b>Chest X-ray scale (grade)</b>				
POD1		1.3 ± 0.8	1.1 ± 0.8	0.34
POD3		1.0 ± 0.9	0.9 ± 1.0	0.76

Post-removal		1.3 ± 0.8	1.2 ± 1.1	0.65
<b>Fluid retention rate (scale)</b>				
POD1		16 (16.3 %)	9 (9.2 %)	0.13
POD3		13 (13.3 %)	13 (13.3 %)	0.90
Post-removal		20 (20.4 %)	18 (18.4 %)	0.80
<b>Pain (Visual Analogue Scale)</b>				
POD 1		5.5 ± 1.9 <b>6.0 ± 1.8</b>	4.6 ± 1.7 <b>5.0 ± 1.5</b>	<b>0.02</b>
POD 3		4.0 ± 1.5 <b>4.0 ± 2.0</b>	4.2 ± 1.8 <b>4.0 ± 3.3</b>	0.70
POD 5		2.8 ± 1.6 <b>2.0 ± 2.0</b>	2.4 ± 1.2 <b>2.0 ± 0.25</b>	0.14
<b>Tube Removal Complications</b>				
Overall	22 (22.4 %)	13 (13.3 %)	9 (9.2 %)	<b>0.47</b>
Pneumothorax	14 (14.3 %)	8 (8.2 %)	6 (6.1 %)	
Pleural Effusion	5 (5.1 %)	3 (3.1 %)	2 (2.0 %)	
Hydro-pneumothorax	2 (2.0 %)	1 (1.0 %)	1 (1.0 %)	
Subcutaneous emphysema	1 (1.0 %)	1 (1.0 %)	0 (0.0 %)	

Data are **number (%)** or mean ± standard deviation (**former**) and **median ± inter-quartile range (latter)**. ICU = Intensive Care Unit; POD= postoperative day; p-value ≤ 0.05 are considered statistically significant.

**Tab. 3** Cost analysis

	STANDARD	COAXIAL	MEAN DIFFERENCE	p-value
Chest tubes cost	21.7	64.5	42.8	
Drugs cost (mean)	16	15.9	0.1	
Hospital cost per days	674	674	0	
Mean length of stay (days)	7.3	6.1	1.2	
<b>TOTAL COST</b>	5059	4273	786	<b>0.04</b>

Costs are indicated in euro. Total cost = (hospital daily cost + cost of drugs)\* mean length of stay + chest tubes cost (once).

## Figures

Image not available with this version

### Figure 1

Smart Drain Coaxial tube (A). These tubes consist of four external fluted channels for fluids drainage and an internal section which allows separate air evacuation from appropriate distal bores (B-C-D).