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Final Report of the European Multi-Center Registry Using the Duett™ Vascular Sealing Device

Sigmund Silber[1], Arne J. Tofte[2], Tor O. Kjellevand[2], Eberhard Grube[3], Gary Gershony[4]

Abstract: Duett™, a novel vascular sealing device, was first clinically used in July 1997. A European multi-center registry was established to evaluate the safety and procedural success of the Duett™ sealing device in a broad range of patients undergoing diagnostic or interventional endovascular procedures.

At 25 European sites 1587 patients were enrolled. All patients (≥ 18 years) must have given informed consent for the use of the sealing device after a diagnostic and/or interventional endovascular procedure performed via a femoral arterial approach. Standard length (≤ 10 cm) 5 to 9 F introducer sheaths had to be used. An ACT of ≤ 400 s, and any approved GP IIb/IIIa platelet receptor antagonist was permitted.

Successful deployment could be achieved in 96.2% (1526/1587 patients) with complete hemostasis within 2 to 5 minutes in over 95% of the patients. The complication-free rate was 96.4%. Arterial occlusions were rare (4 patients) and successfully treated with surgical repair in 1 and with thrombolysis in 3 patients. Pseudoaneurysms occurred in 34 patients, the majority (30/34) were successfully treated with ultrasound-guided compression or resolved spontaneously. The total rate of major complications was 2.6% (41/1587).

The final results of the European registry demonstrate that the Duett™ sealing device can be used with a high procedural success following diagnostic and interventional endovascular procedures. The incidence of major complications is low and comparable to all other approved vascular closure devices and manual compression. CE-mark certification was approved at the end of 1998.

Key Words: Vascular sealing devices · Local complications · Cardiac catheterization · PTCA

Endgültige Ergebnisse des Europäischen Multicenterregisters für das Duett™-Verschlußsystem

Zusammenfassung: Duett™, ein neues arterielles Verschlußsystem, wurde zum ersten Mal im Juli 1997 klinisch eingesetzt. Um die Sicherheit und Wirksamkeit bei einem breiten Spektrum von Patienten nach diagnostischem bzw. interventionellem Katheter zu beurteilen, wurde ein Europäisches Multicenterregister eingerichtet.

An 25 europäischen Zentren wurden 1587 Patienten in das Register aufgenommen. Alle Patienten (≥ 18 Jahre) mußten sich mit der Anwendung des Verschlußsystems (femoraler Zugang) einverstanden erklären. Bei der Katheteruntersuchung sollte ein Schleusendurchmesser von 5 bis 9 F bei einer Standardlänge bis zu 10 cm verwendet werden. Die ACT sollte nicht über 400 s betragen, die zusätzliche Gabe eines zugelassenen GP-IIb/IIIa-Rezeptorantagonisten war gestattet.

Das Verschlußsystem konnte in 96,2% (1526/1587 Patienten) erfolgreich eingesetzt werden, eine vollständige Hämostase trat innerhalb von zwei bis fünf Minuten bei über 95% der Patienten ein. Bei 96,4% der Patienten wurden keine Komplikationen beobachtet. Ein intraluminaler Verschluß der Femoralarterie war selten und wurde erfolgreich operativ bei einem und mittels Thrombolyse bei drei Patienten behandelt. Bei drei Patienten war eine Bluttransfusion erforderlich. 30 der 34 beobachteten Pseudoaneurysmen konnten ultraschallgestützt erfolgreich komprimiert werden oder bildeten sich spontan zurück. Da entsprechend der FDA-Definition auch diese Pseudoaneurysmen als größere Komplikation klassifiziert werden müssen, errechnete sich eine Gesamtrate an größeren Komplikationen von 2,6% (41/1587).

Die endgültigen Ergebnisse des Europäischen Multicenterregisters zeigen, daß das Duett™-Verschlußsystem sicher und erfolgreich nach diagnostischer und interventioneller Katheteruntersuchung eingesetzt werden kann. Die Rate an größeren Komplikationen ist mit der aller anderen zugelassenen arteriellen Verschlußsysteme sowie der manuellen Kompression vergleichbar. Die CE-Zertifizierung wurde Ende 1998 erteilt.

Schlüsselwörter: Arterielle Verschlußsysteme · Periphere Komplikationen · Herzkatheter · PTCA

[1]Dr. Müller Hospital, Munich, Germany,
[2]Rikshospitalet, University of Oslo, Oslo, Norway,
[3]Siegburg Hospital, Siegburg, Germany,
[4]John Muir Medical Center, Walnut Creek, California, USA.

With over 70,000 deployments per month, vascular closure devices are being increasingly used worldwide after diagnostic and therapeutic cardiac catheterizations. Independent of their various concepts (collagen plug, intra-arterial anchor/collagen combination, thrombin/collagen procoagulant or vascular suture), all sealing devices have shown to significantly reduce time to hemostasis [1, 2, 8, 12, 14, 17–21, 25].

Duett™, a novel vascular sealing device, was first clinically used in July 1997 [22]. A European multi-center registry was established to evaluate the safety and procedural success of the Duett™ sealing device in a broad range of patients undergoing diagnostic or interventional endovascular procedures. This report represents the final results of the European registry.

Patients and Methods

The Duett™ Sealing Device

The Duett™ sealing device (Vascular Solutions Inc., Minneapolis, Minnesota, USA) has previously been described in detail [10, 22, 26]. In brief, it provides a rapid physiological closure through the use of a balloon catheter and a flowable procoagulant mixture. The Duett™ device fits 5 to 9 F introducer sheath sizes of standard lengths. Its spherical 6-mm diameter distal balloon is used to create immediate temporary hemostasis, as a depth locator for precise placement of the procoagulant and as a backstop to prevent the procoagulant from leaking into the artery. A proximal "pilot" balloon is used to verify distal balloon inflation. The flowable mixture of thrombin, collagen and diluent is delivered through the sheath sidearm to the puncture site and subcutaneous tissue tract to form a permanent seal. The bovine thrombin (which has been sold in the USA for over 10 years) converts endogenous fibrinogen to fibrin. The microfibrillar bovine collagen (which has been sold in the USA for over 25 years) predominantly serves as a matrix for thrombin and additionally stimulates platelet adhesion and activation.

After the procoagulant is delivered to the adventitial surface via the sheath sidearm (no exchange of sheath is necessary), the balloon is deflated, stretched by the movable core wire, covered by the low profile sleeve and removed from the artery without disruption of the arterial seal. Then, manual pressure is maintained for 2 to 5 minutes to complete sealing.

The Registry

At 25 European sites 1587 patients were enrolled between 15 June 1998 and 31 January 1999.

Inclusion criteria were as follows: All patients (≥ 18 years) must have given informed consent for the use of the Duett™ sealing device after a diagnostic or interventional endovascular procedure performed via a femoral arterial approach. Standard length (≤ 10 cm) 5 to 9 F introducer sheaths had to be used. An activated clotting time (ACT) of ≤ 400 s, and any approved GP IIb/IIIa platelet receptor antagonist were permitted.

Patients with known hypersensitivity to bovine-derived materials or suspected puncture distal to the common femoral artery bifurcation were excluded. Also excluded were patients with clinically severe peripheral vascular disease in the affected limb, defined as: severe claudication (≤ 30 m), weak or absent pulses, ABI < 0.5 at rest, known iliac or femoral artery stenosis ≥ 50%, previous bypass surgery or stent placement in the vicinity of the puncture site.

Results

Successful deployments could be achieved in 96.2% (1526/1587 patients) with complete hemostasis within 2 to 5 minutes in over 95% of the patients.

96.4% of the patients were free of any complication. Device-related complications are listed in Table 1. The most frequent complication was a pseudoaneurysm, which occurred in 34 patients (2.1%). Arterial occlusions were rare (4 patients, 0.3%).

Table 2 lists the treatments of these complications: Surgical repair was necessary in 6 patients (0.4%), blood trans-

Complication	Incidence rate %	(n)
Hematoma < 6 cm	0.4	(6)
Hematoma ≥ 6 cm	0.6	(10)
Bleeding event	0.4	(7)
Pseudoaneurysm	2.1	(34)
Arterial occlusion	0.3	(4)
Infection	0	(0)
Deep venous thrombosis	0	(0)

Table 1. Major and minor device-related complications using the Duett™ sealing device in 1587 patients.

Tabelle 1. Größere und kleinere Komplikationen in Zusammenhang mit der Duett™-Applikation bei 1587 Patienten.

fusion in 3 (0.2%). Inadvertent intra-arterial injection of the procoagulant resulting in arterial occlusion was successfully treated with surgical repair in 1 patient and with thrombolysis in 3 patients. The majority of pseudoaneurysms (30/34) were successfully treated with ultrasound-guided compression or resolved spontaneously.

Discussion

The final results of the European Registry demonstrate that the Duett™ sealing device can be used with a high procedural success following diagnostic and interventional endovascular procedures. The incidence of major complications is low and comparable to all other approved vascular closure devices and manual compression [3–5, 9, 13, 16, 23, 24]. CE-mark certification was approved at the end of 1998.

In prospective open and controlled studies, the Duett™ sealing device has been shown to significantly reduce time to hemostasis and time to ambulation: in its first human feasibility and safety study, time to hemostasis was 2.5 ± 0.9 minutes for diagnostic and 6.0 ± 2.2 minutes for PTCA patients in the reported 24 procedures [22]. The measurements of D-dimer, TAT-3 (thrombin-antithrombin-3 complex) and F1.2 (prothrombin fragments 1 and 2) did not reveal any significant increase in intravascular thrombin generation or activity [22].

A subsequent study in 234 patients (158 diagnostic and 76 interventional patients) reported a time to hemostasis of 3 to 5 minutes, no intra-arterial injection occurred. Three patients developed a pseudoaneurysm (1.3%), which were successfully treated using ultrasound-guided compression. In 3 patients (1.3%), a blood transfusion was given [11].

Complication	Treatment	n
Hematoma < 6 cm	No treatment	6
Hematoma ≥ 6 cm	No treatment	6
	Surgical repair	1
	Blood transfusion	2
	CT-guided drainage	1
Bleeding event	No treatment	6
	Blood transfusion	1
Pseudoaneurysm	Resolved spontaneously	3
	Ultrasound-guided compression	27
	Surgical repair	4
Arterial occlusion	Thrombolytic therapy	3
	Surgical repair	1

Table 2. Consequences following the device-related complications as described in Table 1. No treatment was required in 21 (inlcuding 3 spontaneously resolved pseudoaneurysms), blood transfusion in 3 patients and surgical repair in 6 of the 1587 patients.

Tabelle 2. Konsequenzen der in Tabelle 1 aufgeführten Komplikationen: bei 21 Patienten war keine Behandlung nötig (einschließlich der drei spontan zurückgebildeten Pseudoaneurysmen), bei drei Patienten war eine Bluttransfusion und bei sechs der 1587 Patienten eine operative Korrektur erforderlich.

In the USA, the feasibility trial was conducted in 43 patients who had undergone a cardiovascular procedure at 2 centers [15]. Time to hemostasis was 2.5 ± 0.7 minutes in the 29 diagnostic patients and 4.6 ± 2.1 minutes in the 14 interventional patients (with ReoPro® 4.2 ± 0.6 minutes). Mean time to ambulation was 2.0 ± 0.5 hours in the diagnostic and 5.4 ± 2.0 hours in the interventional group [15].

Recently, the multi-center controlled SEAL-study was presented [7]: At 15 clinical sites (14 in USA, 1 in Germany), 630 patients after diagnostic or interventional coronary procedure were randomized 5 : 3 to the Duett™ sealing device or to standard manual compression. The primary study endpoints were time to hemostasis and time to ambulation. In 126 diagnostic patients receiving the Duett™, the mean time to hemostasis (from case completion) was significantly reduced from 38 minutes (83 diagnostic, manual compression patients) to 12 minutes. In 266 interventional patients receiving Duett™, the mean time to hemostasis (from case completion) was significantly reduced from 297 minutes (155 patients receiving manual compression) to 14 minutes. The corresponding results for time to ambulation were a significant reduction from 359 to 155 minutes in the diagnostic patients and from 960 to 385 minutes in the interventional patients [7].

In the European multi-center registry – according to the nature of registries – time to hemostasis was not as precisely measured as in the above mentioned randomized controlled trials. Successful hemostasis within 2 to 5 minutes could be achieved in over 95% of the reported 1587 patients. According to FDA-definitions, pseudoaneurysms have to be classified as major complications, even if ultrasound-guided compression treatment was successful. With pseudoaneurysms occurring in 34 patients (2.1%), need for blood transfusions in 3 and arterial occlusions in 4 patients, the rate of major complications has to be calculated as 2.6% (41/1587).

None of the currently approved sealing devices has been shown to reduce major local complications as compared with standard manual compression [3–5, 7, 9,

13, 16, 23, 24]. Therefore, vascular sealing devices are predominantly used to increase patient comfort and to reduce the post-procedure patient care burden on the medical staff. Vascular sealing devices may avoid the need for patient hospitalization after diagnostic procedures and decrease the length of hospital stay following coronary interventions [6].

Participating centers (in alphabetical order):
A. Both, Stuttgart, Germany; P. Braun, Duisburg, Germany; W. Dänschel, Chemnitz, Germany; G. Gaul, Vienna, Austria; E. Grube, Siegburg, Germany; B. Hennen, Homburg, Germany; G. Heyer, Salzburg, Austria; W. Höpfner, Augsburg, Germany; H. Jäger, Dortmund, Germany; I. Kassis, Hellerup, Denmark; S. Klugaman, Milano, Italy; D. Lommel, Gießen, Germany; D. Mathey, Hamburg, Germany; E. Maurer, Wels, Austria; G. Norman, Vienna, Austria; P. Probst, Vienna, Austria; N. Reifart, Bad Soden, Germany; G. Rieß, Munich, Germany; K. I. Savnamäki, Copenhagen, Denmark; S. Silber, Munich, Germany; B. Simon, Marburg, Germany; J. Sykora, Klagenfurt, Austria; A. J. Tofte, Oslo, Norway; M. Wesser, Suhl, Germany; K. Zygan, Moers, Germany

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Address for Correspondence: Sigmund Silber, MD, Professor of Medicine, Dr. Müller Hospital, Am Isarkanal 36, D-81379 Munich, Germany,
Fon (+49/89) 7421-510, Fax -5131,
e-mail: silber@med.de