表2　婦人科癌術後下肢リンパ浮腫の発現頻度・様式・部位・発生時期

Form/Site	頻度　189/694例　27.2% No. of pts.	Months from an operation to incidence (Median)	P*
Fugitive	93	2.6M	0.001
Continuous	87	9.7M	
Bi-lateral legs	69	3.9M	0.031
Hemi-lateral leg	111	6.7M	

*Wilcoxon test

表3　下肢リンパ浮腫発現に関与する危険因子

卵巣癌（135例）：単変量解析

Factor	Category	No. of pts.	No. of lymphedema	Prevalence of lymphedema	P*
Omentectomy	−	48	11	0.229	0.622
	+	87	17	0.195	
Hysterectomy	None	8	1	0.125	0.643
	Total	93	18	0.194	
	Modified radical	31	8	0.258	
	Radical	3	1	0.333	
Post-operative	−	134	27	0.201	0.207
radiation	+	1	1	1.000	
Intrapelvic lymph	−	2	0	0.000	1.000
node dissection	+	133	28	0.211	
Para-aortic lymph	−	64	8	0.125	0.033
node dissection	+	71	20	0.282	
Total		135	28	0.207	

*Fisher's exact test

表4　下肢リンパ浮腫発現に関与する危険因子

子宮癌（559例）：単変量解析

Factor	Category	No. of pts.	No. of lymphedema	Prevalence of lymphedema	P*
Omentectomy	−	534	153	0.287	0.821
	+	25	8	0.320	
Hysterectomy	None	4	3	0.750	0.207
	Total	118	35	0.297	
	Modified radical	168	44	0.262	
	Radical	269	79	0.294	
Post-operative	−	423	111	0.262	0.022
radiation	+	136	50	0.368	
Intrapelvic lymph	−	12	4	0.333	0.751
node dissection	+	547	157	0.287	
Para-aortic lymph	−	465	128	0.277	0.261
node dissection	+	94	32	0.340	
Total		559	161	0.288	

*Fisher's exact test

表5　下肢リンパ浮腫発現に関与する危険因子

Origins of cancer	Factor	Category	OR	95%CI	*P
		：多変量解析			
Ovary	Para-aortic lymph node dissection	−	1.00	1.11−6.78	0.029
		+	2.75		
Uterus	Post-operative radiotherapy	−	1.00	1.08−2.46	0.019
		+	1.63		

*Logistic regression model

表6　下肢リンパ浮腫発現に関する危険群分類

Origins of cancer	Post-operative radiotherapy	Para-aortic lymphnode dissection	No. of pts.	OR	95%CI	Risk
Ovary	−/+	−	64	1.00	−	Low
	−/+	+	71	2.75	1.11−6.77	Int.
Cervix	−	−	132	2.15	0.93−4.99	Int.
	−	+	19	4.08	1.24−13.43	High
	+	−	98	4.06	1.74−9.48	High
	+	+	9	5.60	1.24−25.32	High
Endometrium	−	−	212	2.39	1.07−5.34	Int.
	−	+	60	3.24	1.29−8.13	High
	+	−	23	3.73	1.20−11.60	High
	+	+	6	3.50	0.55−22.30	High

Int.：Intermediate

術後の治療としての抗癌剤については有害な危険因子ではない。したがって術後に放射線治療を多く行う子宮頸癌では化学療法を主体にする卵巣癌に比べて，下肢リンパ浮腫の出現は多い。放射線治療を行ったときは何らかの下肢リンパ浮腫の出現予防の対策をたてることは患者さんのQOLを悪化させないために重要である。

術後の下肢リンパ浮腫の出現は，その出現時期の解析から一時的な軽度のリンパ浮腫が術後早期に起き，繰り返しているうちに永続的な下肢リンパ浮腫になることが考えられ，一過性リンパ浮腫の初回の早期治療が重要であると考えられる。

われわれは下肢リンパ浮腫の予防法の1つとして，婦人科癌の術式を工夫することで，術後下肢リンパ浮腫を減らすことができるのではないかと考えた。下肢リンパ浮腫の発生を減らす術式の試みについては従来その1つとして，後腹膜の開放を行うことで下肢リンパ浮腫の出現を減少できるとの報告がある[3, 4]。その根拠としては，術後リンパ嚢腫の有無が下肢リンパ浮腫の発現に関与している可能性である。児玉らはリンパ嚢腫の有無により下肢リンパ浮腫の発現率がそれぞれ35.0%，12.3%とリンパ嚢腫を認めた場合，下肢リンパ浮腫の発現率が有意に高かったと報告している[3]。さらに児玉らは腹膜縫合の有無により，リンパ嚢腫，下肢リンパ浮腫の発現頻度を比較し，腹膜縫合を行わなかった群でともに低かったと報告している[3]。同様にTanakaらも腹膜閉鎖群，開放群でリンパ浮腫の発現頻度を比較し，それぞれ51.0%，25.0%と開放群で有意に低かったと報告している[4]。このように後腹膜の開放はリンパ嚢胞の発現率を減じ，さらには下肢リンパ浮腫の発現率を減ずる可能性がある。しかし従来の報告はすべてヒストリカルコントロールとの比較であり，いまだ十分なエビデンスはない。そのためこれを検証するため現在，われわれは無作為試験を進行中である。

リンパ管・静脈吻合術のPhase II Studyでは

表7　リンパ管・静脈吻合を施した症例背景

Case	Age	PS	Stage	Histology	Medical therapy	Type of Anastomosis				Lymphedema		Survival
						Right Suprainguinal		Left Suprainguinal		Right	Left	
						External	Internal	External	Internal			
1	59	0	Ⅲa	CS	IAP	E to S	E to E	E to E	E to E	Grade Ⅰ	(−)	Alive, NED at 66mo
2	49	0	Ⅰa	EAD G1	MPA	E to E	E to E	E to E	E to E	(−)	(−)	Alive, NED at 65mo
3	50	0	Ⅲc	EAD G2	AP	E to E	E to E	E to E	Sleeve	(−)	(−)	Alive, NED at 62mo
4	58	0	Ⅰa	EAD G1	MPA	E to E	E to E	E to E	E to E	(−)	(−)	Alive, NED at 60mo
5	61	0	Ⅰb	EAD G1	−	E to E	E to E	E to E	E to E	Grade Ⅰ	(−)	Alive, NED at 59mo
6	35	0	Ⅲc	EAD G3	AP	E to E	E to E	E to E	E to E	(−)	Grade Ⅰ	Alive, NED at 57mo
7	59	0	Ⅰa	EAD G3	AP	E to E	E to E	E to E	Sleeve	(−)	(−)	Alive, NED at 57mo
8	42	0	Ⅰa	EAD G1	−	E to E	Sleeve	E to E	E to E	(−)	(−)	Alive, NED at 52mo

PS: Performance status; CS: carcinosarcoma; EAD: endometrioid adenocarcinoma; IAP: ifosfamide, farmorubicin, cisplatin; MPA: medroxyprogesterone acetate;
AP: adriamycin, cisplatin; NED: no evidence of disease;
E to E: end to end Lymphaticovenous anastomosis; sleeve: sleeve anastomosis; E to S: end to side Lymphaticovenous anastomosis

いまだ研究が遂行中であるが，長期経過観察ができた8例では，3例にGrade Ⅰの一過性リンパ浮腫が出たのみであった。登録対象とした子宮体癌の傍大動脈～骨盤内リンパ節郭清例では27%程度のGrade Ⅱ以上の下肢リンパ浮腫が予想されることから，QOL改善の上では役に立つ可能性が考えられる。またGrade Ⅰのリンパ浮腫の発現時も2例は術後すぐでその後改善。他1例は50ヵ月後であり一過性であり，後方視的成績は術後3年間の検討であることから，単純に両研究を比較できない。さらに，今回のPhase Ⅱ Studyでは，後方視的研究に比べ下肢リンパ浮腫の判定がより厳密になっているので単純に頻度からのみ効果を結論はできないと考えられる。今回のわれわれが行った後方視的研究での医師が判定した下肢リンパ浮腫の頻度に比し，Tanakaらの行った患者さんへのアンケート調査ではその頻度が2倍近く高いことより，より角度の高いstudyとしては下肢リンパ浮腫の判定を統一した無作為化試験が必要かもしれない。

本研究では後腹膜腔でのリンパ管・静脈吻合は，術後下肢リンパ浮腫の出現を軽減できる可能性が示唆された。今後さらに22例まで症例を重ね，統計的有意差を確認する予定である。

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原　著

子宮頸がん検診へのベセスダシステム2001導入による不適正検体の頻度の実際とその推移

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目的：子宮頸がん検診にベセスダシステム2001を導入し，不適正検体の頻度の実際とその推移について検討を行った．

方法：2009年4月から千葉県柏市の子宮頸がん検診にベセスダシステム2001を導入した．2009年4月～2010年1月までの10ヵ月間に個別検診で採取された検体11090例，および2009年11月～2010年1月までの3ヵ月間に数人の医師によって行われた車検診による集団検診で採取された4424例の検体について不適正率を調査した．その結果をベセスダシステム2001が導入される以前の2008年1年間の個別検診のデータと比較検討した．すべての検体はちば県民保健予防財団にて診断し，個別検診については1ヵ月ごとに不適正率を各施設に報告した．

成績：ベセスダシステム2001導入以前の個別検診における不適正率は0.11%であったのに対して，導入後の個別検診における不適正率は10ヵ月間で1.36%であり，月別には6.25%から0.40%へ時間の経過とともに低下した．また車検診による集団検診では不適正率は0.07%であった．

結論：不適正検体の報告を各施設に頻回に行うこと，また，少人数の医師が集中して細胞診の検体採取を行うことが，不適正率の低下に寄与することが示唆された．

Key words：Uterine cervical cancer screening，The 2001 Bethesda System，Unsatisfactory rate

I. 背景および目的

「日本産婦人科医会」がん対策委員会は2007年10月に旧日母分類のクラス分類を廃し，ベセスダシステム2001（TBS2001）に準拠した「新日母分類」を承認，2009年度から全国市町村で実施されている行政検診の報告様式をTBS2001[1)]に準拠したものにするように働きかけている．

Actual frequency of unsatisfactory specimens and its changes by introducing The Bethesda System 2001 to cervical cancer screening

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Table 1　Unsatisfactory rate comparison-conventional classification vs TBS 2001

Classification	Conventional	TBS 2001	
Period	Jan. 2008-Dec. 2008	Apr. 2009-Jan. 2010	Nov. 2009-Jan. 2010
Sampling point	Medical facilities	Medical facilities	Screening vehicles
Cases	13112	11090	4424
Unsatisfactory cases (%)	14 (0.11)	151 (1.36)	3 (0.07)

従来のクラス分類とTBS2001との最も大きな違いの一つは，その結果に不適正というカテゴリーが設けられたことである[2,3]．検診の結果不適正と診断されると，受診者は再度検診施設を受診し，医師は再度検体を採取し，そして再度診断して受診者へ結果を通知することとなり，費用，時間，人手といったリソースが今まで以上に必要となる．そのため，不適正と診断される症例が高頻度であると，検診にTBS2001を導入する大きな障害となることが予想される．今回，TBS2001を子宮頸がん検診へ導入し，実際の不適正検体の頻度とその推移について検討した．

II. 方　　法

2009年4月から柏市の子宮頸がん検診にTBS2001を導入した．導入後2009年4月～2010年1月までの10ヵ月間に行われた個別検診について，1ヵ月ごとに検体の不適正率を調査した．また，2009年11月～2010年1月までの3ヵ月間に車検診による集団検診で採取された検体についても，検体の不適正率を調査した．車検診は数人の医師が交代で検体採取を行った．この結果を，TBS2001の導入前の2008年1年間に行われた個別検診のデータと比較検討した．すべての検体はちば県民保健予防財団にて診断し，個別検診については1ヵ月ごとに不適正率を各施設に報告した．個別検診および集団検診すべての検体は塗抹標本であり，液状検体は含まれていない．

III. 結　　果

不適正率の結果をTable1に示した．TBS2001導入前の2008年1月～2008年12月までの個別検診における検体の不適正率は0.11%（14/13112例）であった．TBS2001導入後，2009年4月～2010年1月までの10ヵ月間の個別検診における検体の不適正率は1.36%（151/11090例）であった．2009年11月～2010年1月までの車検診によって行われた集団検診の結果，不適正検体の頻度は0.07%（3/4424例）であった．個別検診における各施設の1ヵ月ごとのデータをTable2に示した．今回18施設から検体が提出されていた．施設による不適正検体の頻度にはばらつきが認められ，約300例の検体の採取に対して1例も不適正検体がなかった施設もあれば，10%を超える頻度で不適正検体が出現した施設もあった．しかし多くの施設で不適正検体の頻度は時間の経過とともに低下していった．そして全体として，観察開始当初6.25%であった不適正率は10ヵ月間で0.40%に低下した（Fig. 1）．不適正検体と診断された個別検診における151検体および集団検診における3検体はすべて細胞数の不足が原因であった．

IV. 考　　察

FiddaらはTBS2001の導入前の6ヵ月間と導入後の6ヵ月間の比較において不適正率が0.36%（21/5808例）から5.3%（288/5459例）に上昇したと報告しており，そのためTBS2001の導入により再検査のための再受診と費用が必要となると述べている[4]．われわれの検討においても，TBS2001を導入後の10ヵ月間の個別検診における不適正検体の頻度は1.36%であり，導入以前の2008年の0.11%に比較して高い値を示した（Table1）．両者は同じ柏市内の施設で検体が採取され，どちらもちば県民保健予防財団で診断されていることから，検体の採取や処理の状態が大きく変化したとは考えにくい．TBS2001導入以前は不適正検体とする明確な基準がなかったため，TBS2001では不適正となるような細胞数の少ない検体でもそのまま診断が行われていたことが予想された．今回のデータではTBS2001導入前の1年間と導入後の10ヵ月間の比較では0.11%から1.36%へ上昇しているものの，毎月の不適正率の変化をみると，導入直後の4月の6.25%から1ヵ月で急峻な下降を示し，その後5月から1月へも緩やかながら更に下降し（correlation coefficient −0.75（P＝0.01，95% CI −0.95 to −0.26）），5月の2.16%（22/1018例）から最終的に0.4%（5/1249例）まで有意に低下している（p<0.01 p-value is calculated by Fisher's exact probability test）．この理由は，毎月不適正検体について各施設に結果とその理由を報告したことにより，検体を採取する現場の医師がその結果を考慮し，十分な細胞数を確保するためにより入念に細胞を採取するようになったことが考えられる．車検診による検体不適正率は0.07%（3/4424例）であり，このデータは個別検診の最終的な検体不適正率の0.40%（5/1249例）と比較しても有意に低い値であった（p＝0.016 p-value is calculated by Fisher's exact probability test）．車検診による検診の場合

Table 2 Monthly change in per-facility unsatisfactory rate

Facility	Apr. 2009	May 2009	Jun. 2009	Jul. 2009	Aug. 2009	Sep. 2009	Oct. 2009	Nov. 2009	Dec. 2009	Jan. 2010	Total
1	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0/11	0/35	0/29	0/39	0/23	0/24	0/42	0/34	0/31	0/27	0/295
2	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0/2	0/13	0/10	0/19	0/16	0/18	0/56	0/47	0/49	0/40	0/270
3	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0/8	0/22	0/23	0/29	0/30	0/25	0/40	0/29	0/31	0/32	0/269
4	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0/1	0/7	0/3	0/7	0/3	0/4	0/8	0/3	0/6	0/10	0/52
5	0%	0%	0%	0%	0%	0%	3.70%	0%	0%	0%	0.43%
	0/11	0/25	0/29	0/34	0/17	0/31	1/27	0/15	0/20	0/23	1/232
6	5.56%	0%	1.96%	0%	0%	0%	0%	0%	2.17%	0%	0.68%
	1/18	0/31	1/51	0/60	0/34	0/40	0/63	0/50	1/46	0/50	3/443
7	0%	6.67%	0%	0%	0%	0%	0%	0%	0%	4.35%	0.85%
	0/10	1/15	0/16	0/27	0/14	0/26	0/47	0/29	0/28	1/23	2/235
8	0%	4.17%	1.45%	0%	0%	2.82%	0%	0%	1.33%	0%	0.97%
	0/19	2/48	1/69	0/78	0/46	2/71	0/84	0/68	1/75	0/58	6/616
9	7.69%	3.57%	0%	0%	0%	0%	1.54%	0%	3.13%	0%	1.09%
	1/13	1/28	0/34	0/48	0/43	0/32	1/65	0/40	1/32	0/33	4/368
10	11.1%	0.76%	1.98%	0.32%	0.48%	1.66%	1.51%	0%	0%	0%	1.16%
	11/99	2/263	5/235	1/318	1/208	4/241	6/398	0/255	0/276	0/298	30/2591
11	5.56%	2.67%	2.5%	0%	0%	0.84%	2.54%	2.63%	0%	0%	1.28%
	1/18	2/75	2/80	0/126	0/72	1/119	3/118	3/114	0/116	0/100	12/938
12	0%	0%	0%	0%	0%	8.33%	1.67%	0%	0%	2.63%	1.32%
	0/10	0/24	0/30	0/29	0/25	2/24	1/60	0/30	0/32	1/38	4/302
13	6.45%	4.17%	2.80%	0.85%	0%	1.61%	1.90%	0.82%	0%	0%	1.48%
	2/31	4/96	3/107	1/118	0/79	2/124	2/105	1/122	0/106	0/127	15/1015
14	8.10%	1.81%	2.19%	3.11%	4.03%	1.39%	1.40%	1.08%	0%	0%	1.75%
	3/37	3/161	4/183	7/225	6/149	2/144	4/285	2/185	0/190	0/212	31/1771
15	5.36%	3.70%	3.18%	1.04%	0%	0.74%	0.87%	1.30%	4.97%	1.81%	2.19%
	3/56	6/162	5/157	2/193	0/134	3/136	2/230	2/154	8/161	3/166	34/1549
16	0%	8.36%	0%	0%	25%	8.33%	5%	7.69%	0%	0%	4.39%
	0/7	1/13	0/9	0/17	1/4	1/12	1/20	1/13	0/9	0/10	5/114
17	0%	0%	25%	0%	50%	0%	0%	0%	0%	0%	9.52%
	0/0	0/0	1/4	0/4	1/2	0/4	0/1	0/2	0/2	0/2	2/21
18	0%	0%	0%	100%	0%	0%	50%	0%	0%	0%	22.2%
	0/1	0/0	0/0	1/1	0/0	0/2	1/2	0/2	0/1	0/0	2/9
Total	6.25%	2.16%	2.06%	0.87%	1.00%	1.58%	1.33%	0.76%	0.91%	0.40%	1.36%
	22/352	22/1018	22/1069	12/1372	9/899	17/1077	22/1651	9/1192	11/1211	5/1249	151/11090

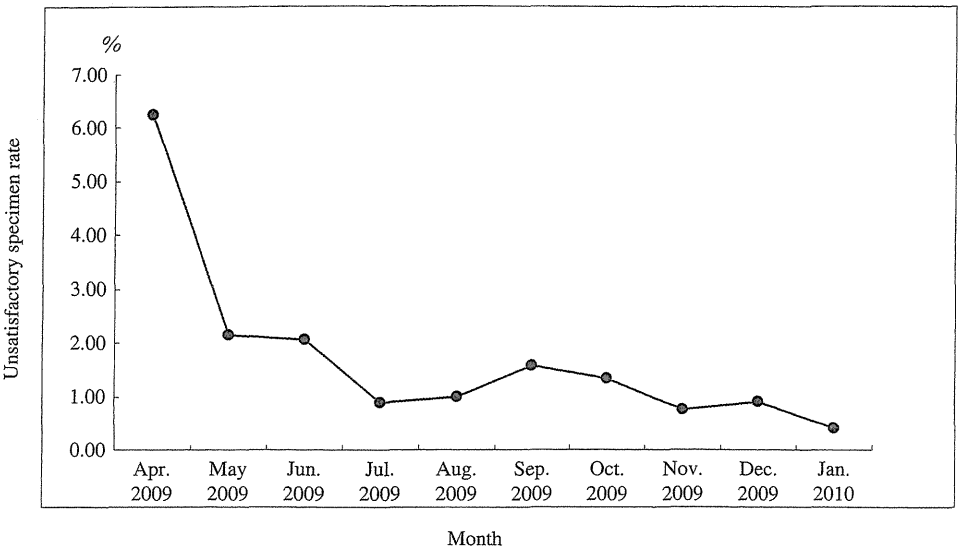

Fig. 1　Change in unsatisfactory specimen rate

は実際に検診車に乗って検体を採取するにあたり，数人の医師が交代で行っている．このため車検診のデータは同一の施設において数人の医師が採取した4424検体が対象である．これに比較して個別検診のデータは18の異なった施設で，少なくとも18人以上の医師が採取した11090例の検体が対象である．少人数の医師が同一施設で集中して採取した車検診による検体の方がばらつきは出にくく，このことが低い不適正率の理由の一つと考えられる．また，車検診においては検診を行う医師がTBS2001の導入以前にその詳細を十分に理解しており，最初から必要充分な細胞数を確保することを念頭におき入念に検体採取をしたことが予想される．今回個別検診においては受診時や受診後の受診者の情報は収集されていないため不明であるが，車検診に関しては検診を受けた後の出血や痛みに関する問い合わせは通常1年間に1件程度であったが，TBS2001を導入後の3ヵ月間で7件と増加し，以前から同じ検診を受けているが今回初めて痛みとその後の出血があったとの意見も含まれていた．このことは，従来よりも多くの細胞を採取しようとしたことに起因すると考えられ，同様のことは個別検診においても起こることが十分予想される．受診者の不安を軽減するためにも，十分な細胞量を採取するためには以前に比較して軽度の痛みや出血の可能性があることを事前に受診者に知らせておくことも重要であると思われた．他施設からのTBS2001導入後の検体不適正率の報告をTable3に示す[4~7]．不適正率は0.81%～5.3%であり，これらの報告と比較すると今回の結果は，個別検診，集団検診ともに良好な結果であったと考えられる．

検体の採取器具も重要な要素であると予想されるが，今回は同一施設でも複数の医師がそれぞれ好みの器具を用いており，すべての検体について正確な採取法のデータが得られなかった．また検体の処理法については，今回はすべて塗抹標本であり液状検体は含まれていない．検体の処理法についての違いについても今後の検討課題であると考えられる．

Table 3　Post-2001 unsatisfactory rate

Authors	Year	Specimen collection	Unsatisfactory rate % (cases)
Fidda N et al.	2004	CVS	5.3 (288/5459)
Chieng DC et al.	2004	CVS (40%) and LBP (60%)	0.81 (84/10367)
Prandi S et al.	2006	CVS	1.99 (1689/85012)
Lu CH et al.	2010	CVS	4.5 (252/5662)

Note：CVS：conventional cervicovaginal smears
LBP：liquid-based preparations

今回の結果から，細胞数の不足により不適正検体となることの周知徹底，不適正検体の報告を各施設に頻回に行うこと，また，少人数の医師が集中して細胞診の検体採取を行うことが，不適正率の低下に寄与することが示唆された．

Abstract

Objective：Introducing The 2001 Bethesda System (TBS 2001) in screening, we studied the frequency of unsatisfactory specimens and changes.

Study Design：TBS 2001 was introduced in municipal cervical cancer

screening in April 2009. Unsatisfactory results were extracted from 11,090 specimens collected in individual screening between April 2009 and January 2010 and 4,424 specimens collected by a small number of physicians in mass screening using mobile screening vehicles between November 2009 and January 2010. Results were compared to data collected in individual screening for 1 year in 2008 before TBS 2001 had been introduced. All specimen-based diagnoses were made at the Chiba Foundation for Health Promotion and Disease Prevention, with unsatisfactory individual screening reported monthly to individual facilities.

Results : The unsatisfactory rate in 2008, the year before TBS 2001 introduction was 0.11%. That for individual screening after introduction was 1.36% for 10 months, decreasing over time from 6.25 to 0.40% based on monthly change. The unsatisfactory rate for mass screening using mobile screening vehicles was 0.07%.

Conclusions : Our results suggest that frequent reporting of inadequate specimens to individual facilities and involving a small number of physicians in collecting specimens helps reduce the unsatisfactory rate.

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CLINICAL STUDY

Safety and Efficacy of Primary Metallic Biliary Stent Placement with Tract Embolization in Patients with Massive Ascites: A Retrospective Analysis of 16 Patients

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ABSTRACT

Purpose: To evaluate the safety and efficacy of primary metallic biliary stent placement with tract embolization in patients with massive ascites.

Materials and Methods: Sixteen patients with malignant biliary obstruction and massive ascites (age range, 44–79 y; median age, 59 y) were treated with primary percutaneous stent placement with tract embolization. These patients were unsuitable candidates for endoscopic intervention. Etiologies of biliary obstruction were gastric cancer with hilar nodal metastases (n = 9), pancreatic carcinoma (n = 5), cholangiocarcinoma (n = 1), and gallbladder carcinoma (n = 1). Eight patients had nonhilar lesions and the remaining eight had hilar lesions. Percutaneous accesses to the biliary system and stent placements were performed in a one-step procedure, and catheters were removed with tract embolization with metallic coils.

Results: Stent placement and tract embolization were successful in all patients, without external drainage catheters left in place. Significant reduction of serum bilirubin level was observed in 14 patients (87.5%). No bile peritonitis or intraperitoneal hemorrhage occurred. Major complications included postprocedural cholangitis (12.5%), bloody bowel discharge (6.2%), and right pleural effusion (25.0%). One patient who died 19 days after intervention was deemed to represent a procedure-related mortality. During the survival period (range, 19–175 d; median, 66 d), stent occlusion was noted in two patients at 6 and 159 days after the procedure. Primary stent patency was achieved in 14 patients (87.5%).

Conclusions: Primary biliary stent placement with tract embolization is technically safe and offers an effective palliative treatment option for patients with malignant biliary obstruction and massive ascites when endoscopic intervention is not possible.

ABBREVIATION

PTBD = percutaneous transhepatic biliary drainage

Most patients with malignant biliary obstruction have advanced-stage cancers with dismal prognoses (1). Percutaneous transhepatic biliary drainage (PTBD) and metallic stent placement are established methods to manage malignant biliary obstruction (2–4) when endoscopic intervention is not possible.

The disadvantage of PTBD is its association with hemorrhage, bile leakage, and catheter dislodgment, with reported incidences of less than 5% each (5–8). Especially in patients with massive ascites, PTBD is thought to be relatively contraindicated because of the high risk of intraabdominal bleeding and peritonitis caused by bile leakage, which is believed to be secondary to the presence of a tube passing through ascites (9). As a result, selection of the treatment approach can be difficult in patients with malignant obstructive jaundice and massive ascites who are unsuitable candidates for endoscopic intervention.

Some studies have demonstrated that transhepatic tract

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Table 1. Disease and Treatment Details of Patients Undergoing One-Step Biliary Stent Placement with Transhepatic Tract Embolization

Pt. No.	Age (y)/ Sex	Primary Tumor	Biliary Obstruction	Degree of Biliary Dilation	Puncture Site/No.*	Stents	Paracentesis
1	57/ F	PC	Nonhilar	Moderate	Right/1	2	No
2	59/ M	PC	Nonhilar	Moderate	Right/1	1	Yes
3	72/ M	PC	Nonhilar	Severe	Right/1	1	Yes
4	74/ F	PC	Nonhilar	Mild	Left/1	2	No
5	57/ M	GC	Nonhilar	Moderate	Right/1	1	No
6	65/ M	GC	Nonhilar	Mild	Right/1	1	Yes
7	74/ F	GC	Nonhilar	Moderate	Right/1	1	Yes
8	50/ M	GBC	Nonhilar	Moderate	Right/1	1	No
9	60/ M	GC	Hilar (Bismuth I)	Severe	Left/1	2	No
10	66/ M	GC	Hilar (Bismuth I)	Moderate	Left/1	1	No
11	58/ M	GC	Hilar (Bismuth II)	Moderate	Left/1	4	No
12	52/ M	GC	Hilar (Bismuth III)	Moderate	Right/1	1	Yes
13	68/ F	GC	Hilar (Bismuth III)	Moderate	Right/2	3	No
14	44/ M	PC	Hilar (Bismuth III)	Moderate	Right/2	3	No
15	79/ M	CC	Hilar (Bismuth III)	Severe	Right/1	1	No
16	56/ M	GC	Hilar (Bismuth IV)	Moderate	Right/3	3	No

Note.— CC = cholangiocarcinoma, GBC = gallbladder carcinoma, GC = gastric cancer, PC = pancreatic carcinoma.
* Puncture number refers to the number of accesses into the biliary system.

embolization can prevent the complications associated with percutaneous intervention (10–15). Stent placement in a one-step procedure could immediately resolve biliary obstruction, shortening the duration of placement of the temporary drainage catheter (4,16–18). In addition, percutaneous biliary metallic stent placement with tract embolization performed in a single session might be a favorable method to manage biliary obstruction in patients with massive ascites who are not suitable candidates for endoscopic intervention or in whom endoscopic treatment has failed.

The purpose of the present study was to evaluate the safety and efficacy of primary metallic biliary stent placement with tract embolization in patients with massive ascites.

MATERIALS AND METHODS

Patient Population

This retrospective study was conducted in accordance with the principles of the amended Declaration of Helsinki, and with the approval of the institutional review board. Between July 2005 and June 2010, 16 patients with malignant biliary obstruction and massive ascites, in whom conventional endoscopic drainage failed or could not be performed because of altered anatomy after surgery, were treated with primary percutaneous expandable metallic stent placement. The patient population included 12 men and four women with a mean age of 62 years (median, 59 y; range, 44–79 y; Table 1).

Etiologies of malignant biliary obstruction were gastric cancer with nodal metastases (n = 9), pancreatic carcinoma (n = 5), cholangiocarcinoma (n = 1), and gallbladder carcinoma (n = 1). The diagnosis of biliary obstruction was confirmed by computed tomography (CT) and/or ultrasonography (US; Fig 1a). Eight patients had lesions involving the middle and distal common bile duct, and eight had proximal bile duct (ie, hilar) lesions. The latter were classified according to Bismuth classification as follows: type I, n = 2; type II, n = 1; type III, n = 4; and type IV, n = 1 (Table 1). All 16 patients had massive ascites caused by peritoneal dissemination and/or advanced disease, and five patients had liver metastases. Massive ascites was defined as a large amount of fluid in the paracolic regions and around the liver at the proposed puncture site, and resulted in a tense abdomen determined with imaging and physical examination (9,19). Cytologic examination of the ascites was performed in 12 of 16 patients, and a malignant cytologic result was revealed in nine patients.

In 11 of the 16 patients, endoscopic intervention was attempted, but resulted in failure because of gastroduodenal invasion by the primary disease (n = 8) or rigidity of the papilla of Vater (n = 3). In the remaining five patients, the endoscopic approach was not attempted because of previous surgery with Roux-en-Y conversion.

Procedures

Written informed consent was obtained from all patients before the procedures. All procedures were performed under local anesthesia with 1% lidocaine and conscious sedation with midazolam and pentazocine or fentanyl. Intravenous broad-spectrum antibiotic prophylaxis was routinely administered 6 hours before the procedure in all patients

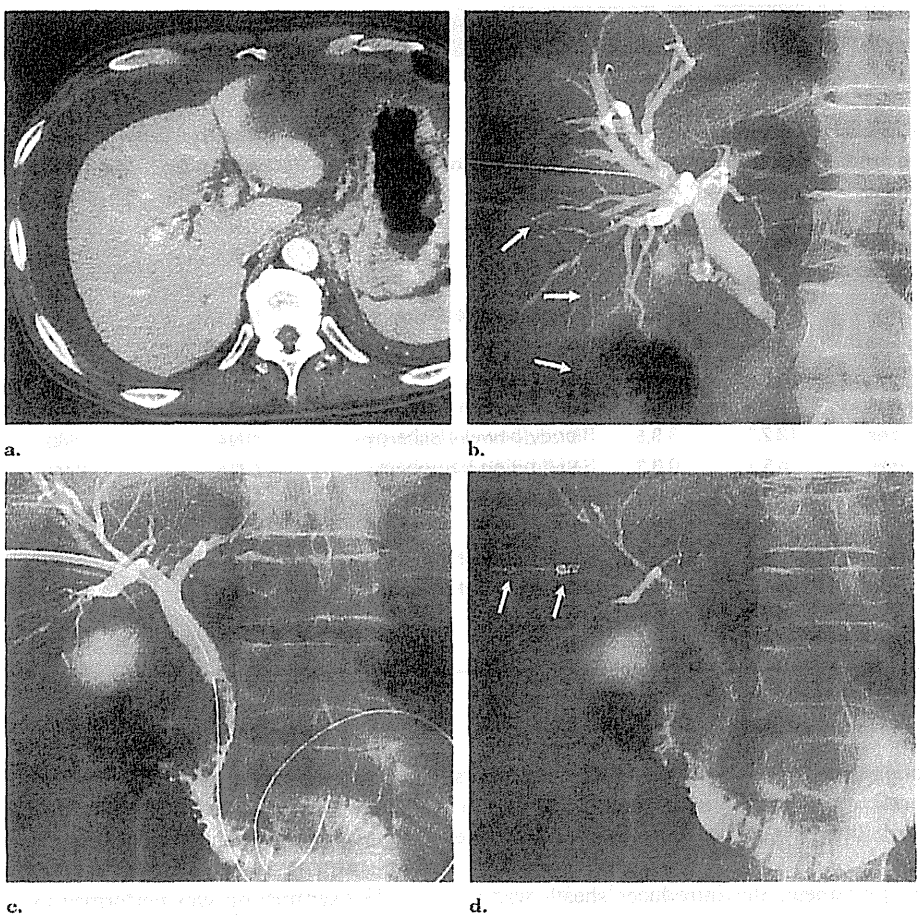


Figure 1. Gastric cancer with nodal metastasis in a 65-year-old man (patient 6; Table 1). **(a)** Contrast-enhanced CT before stent placement shows dilated intrahepatic biliary ducts and massive ascites. **(b)** Percutaneous transhepatic cholangiography reveals tight stricture at the distal common bile duct. Note that a 6-F tube was placed around the liver surface (arrows). **(c)** Cholangiography performed after stent placement shows good expansion of the stent and good flow of contrast material through the stent. **(d)** Embolization of the transhepatic tract was performed with metallic coils (arrows).

and continued for as long as 5 days after the procedure. Percutaneous puncture, insertion of the catheter into the intrahepatic biliary duct, and stent placement were performed in a single session without leaving an external drainage catheter. No patients had suspected cholangitis before the procedure, as we performed stent placement only for patients without combined infection. In five of the 16 patients, 6-F catheters were placed around the liver surface to monitor for intraperitoneal hemorrhage during the procedure before PTBD.

The appropriate intrahepatic bile duct was punctured with a 21-gauze needle (Top, Tokyo, Japan) under US guidance, and percutaneous transhepatic cholangiography was then performed to confirm obstruction of the bile duct (Fig 1b). After placement of a 6.5-F catheter (Seeking catheter; Hanako, Saitama, Japan) and a 0.035-inch angled hydrophilic guide wire (Radifocus Guide Wire M; Terumo, Tokyo, Japan) past the obstruction and into the duodenum, the overall length of the obstruction was confirmed with injection of contrast material. The guide wire was exchanged for a 0.035-inch guide wire (Amplatz Extra-Stiff Guide Wire; William Cook Europe, Bjaeverskov, Denmark), an introducer sheath (Create Medic, Yokohama, Japan) was inserted to increase the diameter of the tract, and the expandable metallic stent was then placed. Uncovered stents were placed through 7-F sheaths, and covered stents were placed through 10-F sheaths. Covered stents were mainly used in patients with aggressive pancreatic cancer based on operator preference. Seven patients who had common bile duct or Bismuth type I obstructions were each treated with a single stent. There were three patients in whom it was difficult to span the distance with a single stent (Table 1). In the six patients with Bismuth type II, III, and IV obstructions, attempts were made to minimize the number of punctures to prevent bile leakage or intraperitoneal hemorrhage as much as possible and to place the minimum number of stents required to drain at least 50% of the liver volume (3). The stents placed in the common bile duct extended 1 cm beyond the papilla of Vater in all patients. All placed stents were fully expanded with predilation (n =

Table 2. Outcomes of Patients Undergoing One-Step Biliary Stent Placement with Transhepatic Tract Embolization

Pt. No.	Clinical Success	Total Bilirubin (mg/dL)		Complications	Stent Occlusion (d)	Survival (d)	Cause of Death
		Before	After				
1	Yes	4.5	0.7	None	NA	61	Progression
2	Yes	5.4	2.7	None	NA	74	Progression
3	Yes	10.8	0.9	None	NA	39	Progression
4	Yes	1.1	0.7	None	NA	86	Progression
5	Yes	4.8	0.7	Right pleural effusion	NA	153	Progression
6	Yes	13.4	2.3	None	NA	66	Progression
7	No	6.4	17.4	Cholangitis	NA	19	Complication
8	Yes	2.7	0.5	Right pleural effusion	159	175	Progression
9	Yes	12.7	3.5	Bloody bowel discharge	NA	43	Progression
10	Yes	5.1	0.3	Self-limiting hemobilia	NA	169	Progression
11	Yes	7.3	3.4	Cholangitis	NA	33	Progression
12	Yes	8.8	0.8	None	NA	56	Progression
13	Yes	7.1	0.7	Right pleural effusion	NA	93	Progression
14	Yes	4.1	1.6	Right pleural effusion	NA	128	Progression
15	Yes	4.3	0.8	None	NA	66	Progression
16	No	8.7	16.4	None	NA	24	Progression

Note.—NA = not applicable.

12) or postdilation (n = 8) with 6–10-mm balloon catheters (Synergy [Boston Scientific, Natick, Massachusetts] or Powerflex [Cordis/Johnson and Johnson, Oosteinde, The Netherlands]).

After stent placement, the introducer sheath was replaced by a 6.5-F catheter, confirming good flow of contrast material through the biliary system (Fig 1c). The biliary access point and distal end of the transhepatic tract were carefully determined by injecting contrast material. Tract embolization was performed by advancing and tightly packing one to three 0.035-inch metallic coils (5 mm × 5 cm, 4 mm × 3 cm, 3 mm × 4 cm; MReye embolization coil; William Cook Europe) through a 6.5-F catheter. The coils were pushed by using a 0.035-inch wire, and the 6.5-F catheter was gently removed (Fig 1d).

Study Endpoints and Definitions

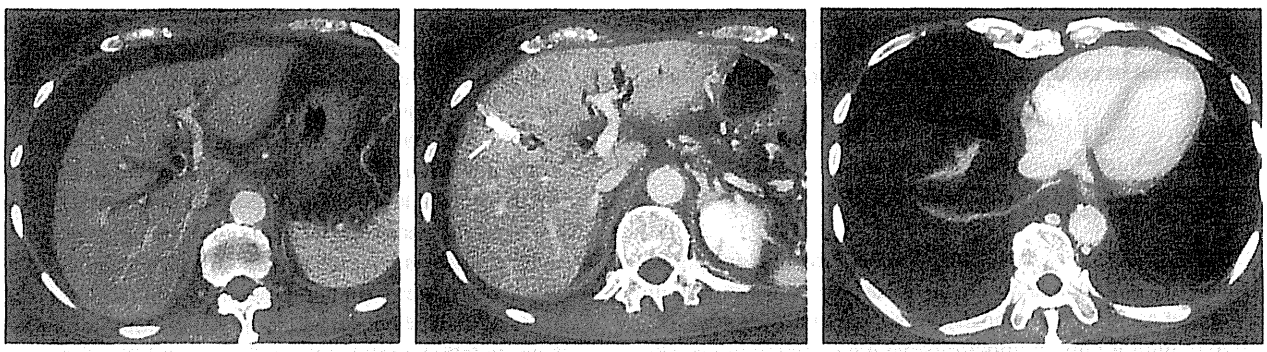
Technical success, clinical success, complications, stent patency, and duration of survival were retrospectively assessed. Technical success was defined as percutaneous transhepatic stent placement in the expected position and successful embolization of the tract without an external drainage catheter left in place. Clinical success was defined as a decrease in serum total bilirubin levels within 30 days of stent placement compared with levels recorded before the procedure. All complications arising from the procedure were divided into major and minor categories according to the reporting standards of the Society of Interventional Radiology (20).

Follow-up, which consisted of clinical examination and laboratory testing, including serum total bilirubin, serum liver enzyme levels, and complete blood count, was performed as needed until the time of death. US examination was performed to assess postprocedural biloma, ascites, and pleural effusion. When total serum bilirubin levels were increased and stent occlusion was suspected, CT or US examination was performed to confirm stent malfunction by dilation of the intrahepatic bile ducts. Stent patency was judged based on the absence of increased total serum bilirubin levels or the absence of dilation of intrahepatic bile ducts on CT or US examination even if total serum bilirubin level was increased. If there was no evidence of stent malfunction during the patient's life, the stent patency period was considered to be equal to the survival period.

RESULTS

Technical Success

Stent placement and tract embolization were successful in all patients without leaving an external drainage catheter, and the technical success rate was 100% (Table 2). All 16 patients received stent placement via the left (n = 4) or right (n = 12) hepatic lobe approach. Two patients received multiple stent placements through two puncture sites on the right, and one patient received three punctures on the right. In each of the remaining 13 patients, stents were placed through one puncture site. One patient received bilateral stent placement through one puncture site on the right in a "T" configuration. Consequently, a total of 20 transhepatic tracts were embolized. A total of 28 expandable metallic stents were inserted according to availability and operator preference. A total of 21 uncovered stents (Zilver; William Cook Europe) were placed in 11 patients, and seven cov-



a. b. c.

Figure 2. Gastric cancer with nodal metastasis in a 57-year-old man (patient 5). **(a)** Contrast-enhanced CT before the procedure shows dilated intrahepatic biliary ducts and massive ascites. **(b)** Contrast-enhanced CT after the procedure revealed improvement of obstructive jaundice and decreased ascitic fluid. Note that the transhepatic tract was tightly packed with metallic coils (arrow). **(c)** Contrast-enhanced CT also showed significantly increased right pleural effusion.

ered stents (VIABIL; W.L. Gore and Associates, Flagstaff, Arizona) were placed in five patients in the common bile duct.

Clinical Success

Reduction of the total serum bilirubin level compared with the preprocedural level was achieved in 14 of 16 patients, yielding a clinical success rate of 87.5%. The mean total serum bilirubin level before the stent placement was 6.7 mg/dL ± 3.5 (SD) (median, 5.9 mg/dL; range, 1.1–13.4 mg/dL), and that after the stent placement was 3.3 mg/dL ± 5.4 (median, 0.9 mg/dL; range, 0.3–17.4 mg/dL). The mean total serum bilirubin levels after the procedure were significantly lower than those before the procedure ($P = .009$).

Clinical success could not be achieved despite the procedure in two patients (12.5%). In one patient who had a Bismuth type IV obstruction, an additional stent was inserted into another intrahepatic biliary duct 6 days after the initial procedure to achieve drainage of the entire liver; however, the patient died 24 days after the procedure without showing any decrease of serum bilirubin level as a result of hepatic insufficiency caused by multiple liver metastases. The other patient, who had a distal bile duct obstruction, died of cholangitis 19 days after the procedure.

Complications

Major complications occurred in seven patients (43.7%), and included postprocedural cholangitis with fever and leukocytosis treated by administration of antibiotic therapy in two patients (12.5%), bloody bowel discharge requiring blood transfusion in one patient (6.2%) who had undergone balloon dilation of a biliary stricture, and right pleural effusion in four patients (25.0%). In one patient who died of cholangitis 19 days after stent placement, the death was judged to be a procedure-related mortality. The patient had distal bile duct occlusion and also had distal intestinal obstruction caused by peritoneal dissemination, and developed reflux cholangitis complicated by sepsis after the procedure, resulting in death. All four patients in whom right pleural effusion occurred received stent placement via the right hepatic lobe approach without paracentesis during the procedure. CT examination after stent placement showed increased right pleural effusion and decreased ascites (Fig 2). The pleural effusions were treated successfully by percutaneous drainage and aspiration over a period of 3–5 days. A diagnostic pleural tap from the right chest did not reveal bile, and laboratory testing of pleural effusion did not show increased total bilirubin levels. No peritonitis caused by bile leakage or intraperitoneal hemorrhage occurred in any of the 16 patients.

A minor complication was seen in one patient (6.2%). Self-limited hemobilia was caused by balloon dilation of biliary stricture and confirmed by cholangiography during the procedure. The patient did not require blood transfusion.

Follow-up

Complete follow-up until death was carried out for all patients. The survival period after stent placement ranged from 19 to 175 days (median, 66 d; mean, 80.3 d ± 50.5). Two patients died within 30 days after the procedure: one accounting for the procedure-related mortality mentioned earlier and another who died 24 days after the procedure because of hepatic insufficiency resulting from multiple liver metastases. The remaining 14 patients died of disease progression.

Of the 14 patients who survived for longer than 30 days after stent placement, three patients (21.4%) showed increased total serum bilirubin levels 37, 46, and 151 days after the procedure. One of these three patients showed stent occlusion, which was confirmed by US examination 159 days after stent placement, and died 175 days after the procedure without any repeat intervention. In the other two patients, no stent occlusion was evident on CT and/or US examination, and the patients died of hepatic insufficiency caused by disease progression 33 and 66 days after stent

placement. Overall, primary stent patency was achieved in 14 of 16 patients (87.5%), and secondary patency was achieved in an additional patient, for a total patency rate of 93.7%.

DISCUSSION

This study demonstrates that tract embolization for percutaneous biliary metallic stent placement in patients with massive ascites is technically feasible and clinically effective, with a limited number of severe complications. These findings indicate that percutaneous biliary stent placement may be considered as a treatment option even in patients with massive ascites when the endoscopic approach is not feasible or has failed.

In this study, adequate stent placement to cover the stricture was successfully performed in all patients, and tract embolization with metallic coils was also successfully carried out in all patients. Our results also show no evidence of bile peritonitis, subcapsular biloma, or intraperitoneal hemorrhage. These findings suggest that tract embolization is quite useful for preventing bile leakage and bleeding into the peritoneal cavity even in patients with massive ascites, as described in some previously published studies (10–13). Conversely, Thornton et al (18) found that a few patients (5.6%) who received primary metallic biliary stent placement had symptoms of bile peritonitis after catheter removal. The discrepant findings may have come about because most of their patients did not undergo tract embolization (three of 52 patients received primary biliary stent placement), and it was not revealed whether these three patients developed bile peritonitis (18). Although Lammer et al (21) also reported simultaneous deposition of compressed gelatin sponge into the transhepatic tract in uncomplicated cases, they documented no precise number of patients who underwent tract embolization. Nevertheless, Thornton et al (18) speculated that immediate removal of the biliary access facilitated by tract embolization might be desirable, and this would have mandated a new biliary drainage procedure for patients with ascites. The present results clarify their speculation.

We used metallic coils to embolize transhepatic tracts because they can be delivered precisely and placed tightly in the appropriate location, although other embolic materials, including gelatin sponges (10), n-butyl cyanoacrylate (11,12,14), AMPLATZER Vascular Plugs (15), and metallic coils (13) have also been used. The use of gelatin sponge or n-butyl cyanoacrylate poses a risk of material migration into the biliary tree, possibly resulting in biliary obstruction, and incomplete embolization of the tract. The AMPLATZER Vascular Plug is reasonable to use in the transhepatic tract but is comparably expensive. In addition to complete tract embolization, optimization of bile flow by full expansion of the stents is crucial in the authors' opinion for the prevention of bile reflux; however, this could not be definitively proven by the present study.

By contrast, a significant right pleural effusion developed in four of 12 patients who were treated by a right hepatic lobe approach without paracentesis. We assume that transpleural puncture associated with the use of a right hepatic lobe approach leads to the leakage of ascites into the pleural cavity. This may have been prevented by a left hepatic approach or large-volume paracentesis before the procedure. In addition, we encountered one patient who died of postprocedure cholangitis. A possible reason is that all the patients in the present study had more advanced disease and were in poorer general condition than patients in other published reports, and this condition predisposed them to lethal complications. This possibility indicates that early infection potentially leads to death in such patients who have advanced disease.

The 87.5% clinical success rate of biliary stent placement in the present study is comparable to those of others (2–5,8). It should be noted that, despite successful drainage of the entire liver, one of two patients who showed clinical failure died of hepatic insufficiency caused by multiple liver metastases. This outcome highlights the fact that biliary intervention does not always lead to clinical improvement in patients with extremely advanced disease, even if adequate drainage can be achieved.

The median and mean survival durations after stent placement in the present study were 66 days and 80.3 days, respectively. This may be attributable to the poor clinical status of the patients in the study. These patients had extremely advanced malignancies, most of which not of hepatobiliary/pancreatic origin. These results are consistent with those reported by Thornton et al (18) and Meller et al (21), who reported poorer survival after biliary stent placement in non–hepatobiliary/pancreatic malignancies than in hepatobiliary/pancreatic malignancies. We consider that primary stent placement with tract embolization might have been beneficial for patients with ascites and a limited survival period, because it provides 100% catheter-free survival and eliminates lifestyle limitation and potential complications such as insertion-site pain, catheter dislodgment, and pericatheter leakage of bile or ascites related to the presence of an external drainage catheter (18). It would be difficult to assess the true stent patency rate because of the short observation of the limited survival period.

The present study has limitations. First, the study design was retrospective, and the sample size was small. However, we are aware of no published that have investigated the efficacy of primary percutaneous biliary stent placement in patients with massive ascites except for one case report (11). The second limitation was the lack of long-term follow-up as a result of the patients' short life expectancies, which limited assessment of long-term stent patency. Finally, no real evaluation of the tract for bile leakage was undertaken in any sort of systemic manner; only a diagnostic tap of ascites and patient-reported abdominal pain were assessed. Despite these limitations and the slightly higher rate of complications than in other studies, we believe percutaneous stent placement with tract embolization in a single session may be an important treatment

option for patients with obstructive jaundice that cannot relieved by endoscopic intervention, in addition to massive ascites.

In conclusion, we report that primary biliary stent placement with coil embolization of the tract is technically safe in patients with massive ascites. It offers an effective palliative treatment option for malignant biliary obstruction when endoscopic intervention is not possible.

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BRIEF REPORT

Anchoring System–Assisted Coil Tract Embolization: A New Technique for Management of Arterial Bleeding Associated with Percutaneous Nephrostomy

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ABSTRACT

Anchoring system–assisted coil tract embolization (AACTE), a new nonvascular treatment technique for massive bleeding associated with percutaneous nephrostomy (PCN), consists of packing the tract with embolization coils, with a balloon catheter used as an anchoring system. After arterial bleeding associated with PCN was successfully treated with AACTE in three patients, no severe complications were noted, and renal function was not affected. AACTE is a potentially useful and safe method for management of vascular complications associated with nephrostomy.

ABBREVIATIONS

AACTE = anchoring system–assisted coil tract embolization, PCN = percutaneous nephrostomy

Percutaneous nephrostomy (PCN) is a well established procedure with a technical success rate greater than 90% even in nondilated renal systems (1,2). Complications of PCN include pain, sepsis, bleeding, damage to adjacent organs, and renal pelvic injuries. Acute bleeding that requires blood transfusions has been regarded as the most life-threatening event associated with PCN, occurring in 2%–4% of patients during this procedure (1,2).

Most patients with persistent venous bleeding can undergo conservative management with deployment of a larger-caliber catheter as a tamponade or placing the patient in a supine position (3,4), although transcatheter arterial embolization may be required in severe cases of arterial damage (1,2,5–7). Although contrast agent allergies and impaired renal function are unfavorable conditions for transcatheter arterial embolization, life-threatening bleeding takes precedence over dialysis, and intervention should be performed. In this article, a new method for treatment of arterial bleeding associated with PCN consisting of an anchoring system–assisted coil tract embolization (AACTE) technique is reported.

MATERIALS AND METHODS

The institutional review board of our institution approved a retrospective medical record research study to review the results of AACTE. Informed consent was obtained from each patient before the implementation of AACTE. This report was conducted in accordance with the amended Declaration of Helsinki.

Patient records were retrospectively reviewed during a 4-year period (January 2007 to December 2010), during which 158 PCNs were performed in 146 patients (92 men and 54 women; mean age, 52 y) in our department (National Cancer Center Hospital and Gunma University Hospital).

The renal systems were dilated in all cases, and PCN was performed to relieve urinary obstructions of benign or malignant nature. The mean serum creatinine level was 4.1 mg/dL (range, 3.5–8.2 mg/dL). The mean follow-up period was 62 days (range, 5–211 d) after PCN. In all patients, coagulopathy was corrected before the procedure.

In all patients who underwent PCN, the calyx of the

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Table. Characteristics of the Three Patients Treated by AACTE

Pt. No.	Age (y)	Primary Disease	Coils Used	Follow-Up (d)	Prothrombin Time (%)	Platelets ($10^3/mm^3$)	Creatinine (mg/dL)
1	62	Bladder carcinoma	6	62	90	20.1	4.1
2	60	Gastric carcinoma	7	94	75	12.8	4.9
3	49	Esophageal carcinoma	7	74	55	9.1	6.1

Note.—All patients were male. Patient 2 had a history of a major allergic reaction to contrast media. AACTE was performed on the right kidney in all patients. AACTE = anchoring system-assisted coil tract embolization.

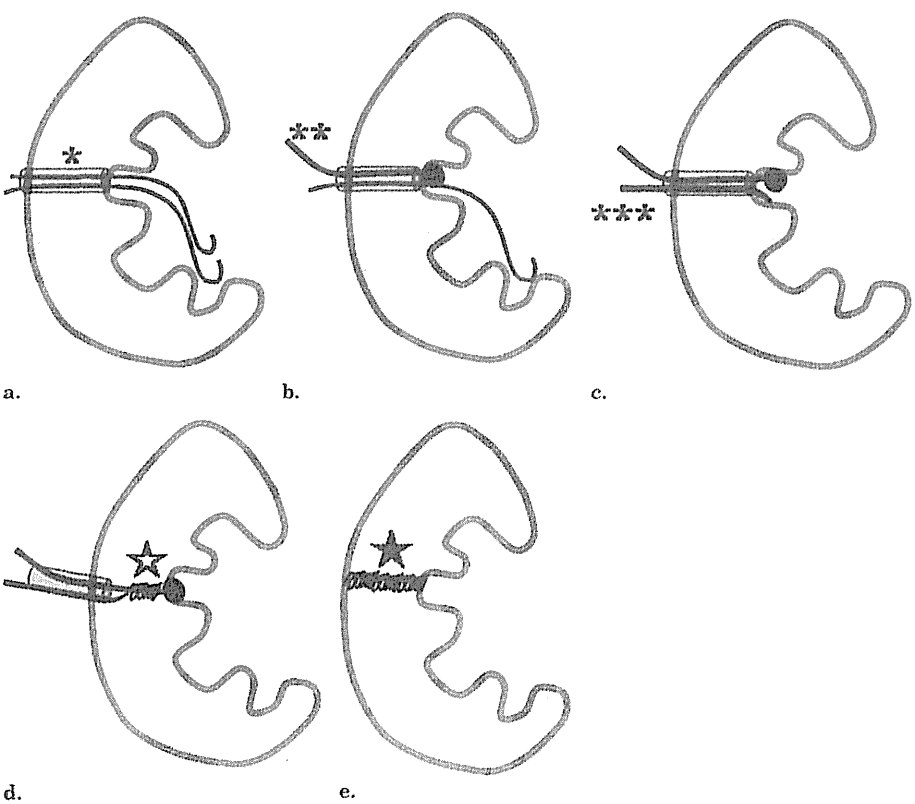

Figure 1. Schematic diagram of AACTE. The PCN tube is exchanged with the 10-F sheath (single asterisk). The sheath is kept in place with two guide wires **(a)**. A balloon catheter (double asterisks) is used as an anchoring device **(b)**. A 6.5-F catheter (triple asterisks) is advanced over the guide wire **(c)**, and metallic coils (white star) are released through the 6.5-F catheter **(d)**. Multiple metallic coils (black star) are packed as tightly as possible in the PCN tract **(e)**.

kidney was punctured with a 17-gauge needle (PTC needle; Hakko, Tokyo, Japan) under ultrasound (US) guidance. A 0.035-inch J-shaped guide wire (Fixed Core Wire Guides, Safe-T-JR Curved; Cook, Bloomington, Indiana) was then advanced through the 17-gauge needle. After tract dilation over the guide wire, a 10-F PCN tube (Malecot catheter; Bard, Salt Lake City, Utah) was advanced over the guide wire.

There were eight patients with suspected vascular injuries associated with PCN; this suspicion was based on continued blood flow from the PCN tract and a decrease in hemoglobin level of more than 2.0 mg/dL (range, 2.0–5.1 mg/dL) was noted. It was difficult to distinguish between arterial and venous injuries. A total of five of these patients recovered after the 10-F nephrostomy tube was used to apply tamponade, and AACTE was employed in three patients who had hydronephrosis of a single functioning kidney. One of these patients (patient 2) had a history of a major allergic reaction to iodinated contrast media. In these three patients, the 10-F nephrostomy tube was changed to a 12-F nephrostomy tube, and the nephrostomy tube was clamped to apply tamponade to temporarily improve the situation. However, the bleeding was not controlled, and arterial bleeding was suspected based on the presence of a forceful flow of pulsatile blood from the PCN tract. Characteristics of the three patients are listed in the Table. In

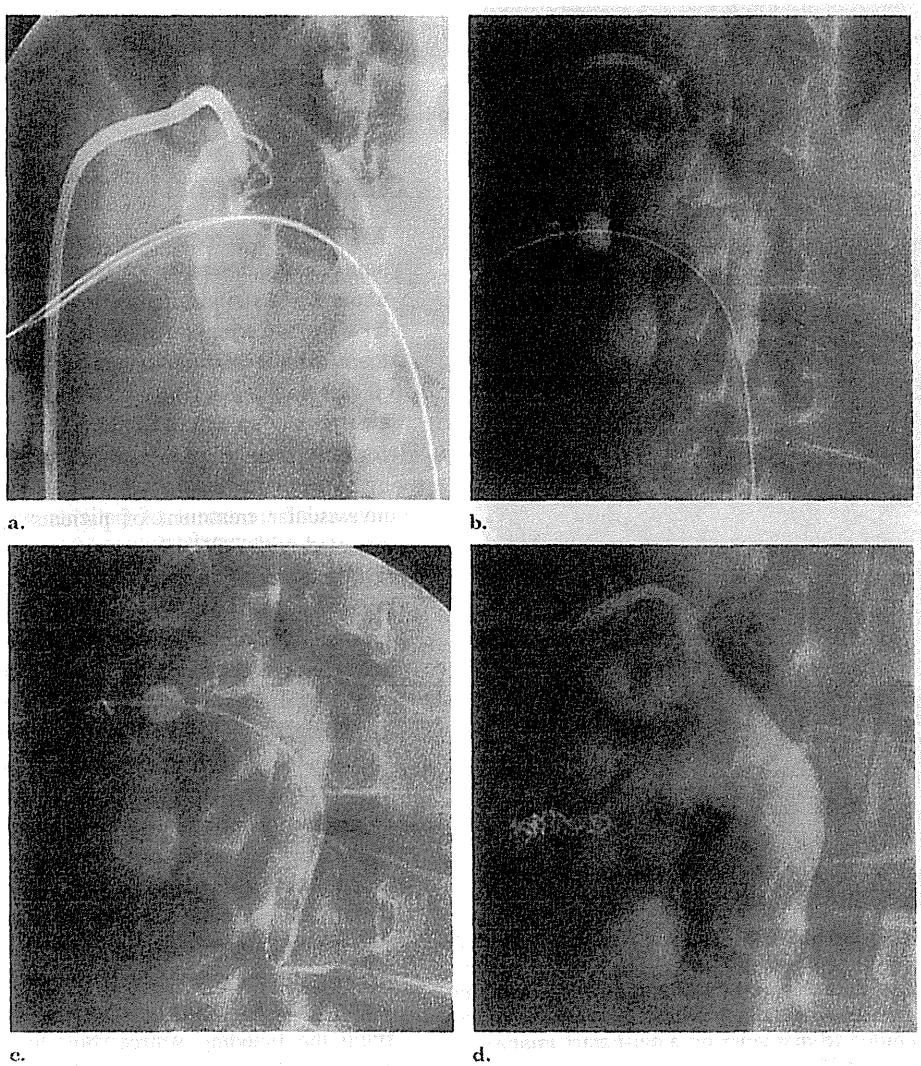

Figure 2. Radiographic images of AACTE. The PCN tube was exchanged with the 10-F sheath, which was kept in place with two guide wires (**a**). A balloon catheter was used as an anchoring device (**b**). A 6.5-F catheter was advanced over the guide wire, and metallic coils were released through the 6.5-F catheter (**c**). Multiple metallic coils were packed as tightly as possible in the PCN tract (**d**).

patient 1, bleeding through the PCN tube was initiated at the time of tract dilation for PCN insertion, and AACTE was attempted immediately. In patients 2 and 3, sudden massive bleeding from PCN commenced on postoperative days 3 and 17, respectively. AACTE was performed on postoperative days 5 and 19, respectively. Patient 3 refused treatment at first, and subsequently developed hemorrhagic shock with 800 mL of blood loss.

AACTE was performed under local anesthesia by using a 0.035-inch J-shaped guide wire inserted into the 10-F PCN tube under fluoroscopy guidance. The tube was then exchanged with a 10-F sheath (Super Sheath; Medikit, Tokyo, Japan). Another 0.035-inch J-shaped guide wire was inserted through the sheath after the first guide wire had been secured; thus, two guide wires kept the route open (**Figs 1a, 2a**). As an anchoring device, a 5-F balloon catheter (9-mm-diameter Selecon MP Catheter II; Terumo/Clinical Supply, Gifu, Japan) was advanced into the renal pelvis over the guide wire and placed as close as possible to the renal pelvic wall to prevent coil migration into the renal pelvis (**Figs 1b, 2b**). This device marked the pelvic side of the bleeding tract and was kept in place during the entire coil deployment. Traction on the occlusion catheter was only intermittently required. The other guide wire was used for insertion of a 6.5-F catheter (Seeking catheter; Hanaco, Saitama, Japan; **Fig. 1c**). After the 10-F sheath was extracted, a tractogram was performed through the sheath to visualize the bleeding point and the edge of the kidney. Metallic coils (0.035-inch, 5 mm × 5 cm; MReye embolization coil; Cook) were packed as tightly as possible in the bleeding tract through a 6.5-F catheter (**Fig 1c, 1d**) until no arterial bleeding was observed through the catheter. The

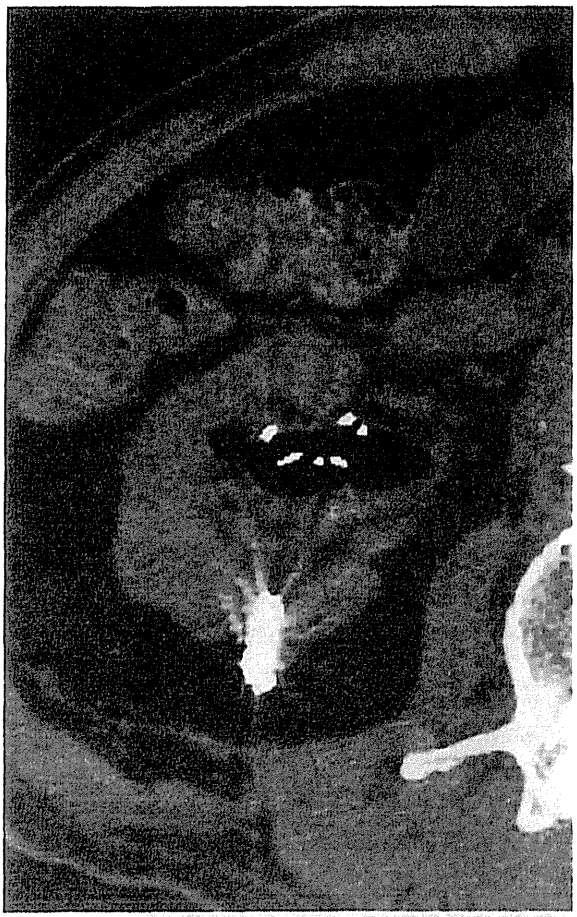

Figure 3. CT image of the right kidney in patient 3 on day 3 after AACTE. Appropriate placement of coils in the PCN tract was confirmed. The coils were also in the perirenal fat. The location of these coils outside the renal parenchyma very closely corresponded to that seen on a final tract image obtained at the time of AACTE.

coils were pushed with a 0.035-inch wire. The two catheters were then removed gently so as not to displace the coils (Figs 1e, 2d). The balloon catheter was removed over a wire to maintain access in case coils were displaced. After enough coils had been placed, there was no profuse bleeding through the tract after the sheath had been removed. A new PCN tube was inserted by US guidance from another route.

RESULTS

In all three cases, hemostasis was achieved immediately after the AACTE, and a decrease in serum creatinine level to less than 2.0 mg/dL (range, 1.5–1.9 mg/dL) was noted on day 7 after the procedure. Unenhanced computed tomography (CT) of the abdomen just after the procedures confirmed appropriate coil placement in the renal parenchyma (Fig 3) in all three cases. No recurrent bleeding events occurred during the follow-up periods (range, 62–94), and no serious complications (eg, renal infarction, renal abscess formation, or migration of coils) were observed on follow-up CT examinations.

DISCUSSION

AACTE was successful as a nonvascular method for managing active hemorrhage after PCN and was performed without any serious complications. To our awareness, there have been two reports of successful transrenal embolization therapy with steel coils placed in the damaged vessels and in the percutaneous tract (8,9). However, those procedures are extremely unusual to enter arterial branches, and therefore those techniques have not been widely used. To the best of our knowledge, AACTE is a novel technique for nonvascular treatment of patients with arterial bleeding associated with PCN.

There are some technical points of AACTE to consider. First, the tract must be totally embolized, and the coils should be placed as tightly together as possible, as the point of bleeding cannot usually be identified in the course of the tract. Second, dislodgment of the coil into the ureter should be prevented, as this may result in renal dysfunction. In the patients described herein, coils were placed tightly in the tract, preventing coil migration into the ureter, by using an anchoring system. Third, two guide wires were inserted into the tract, one for marker device (balloon catheter) insertion and the other for tract embolization.

There are limitations associated with AACTE. First, this method is not useful when the bleeding source is outside of the extraparenchymal area of the kidney. Fistulography of the bleeding tract might be helpful for identifying the bleeding source, but, because of the pressure gradients, these do not always show the bleeding source (1). Second, ACCTE, like transcatheter arterial embolization, might include a risk of renal infarctions despite the fact that it is a nonvascular technique. Peripheral arterial communications in the renal artery may compensate for this problem (10). However, it is also possible that renal artery collaterals will cause persistent bleeding, and the ACCTE technique may work for delayed pseudoaneurysm formation. Third, percutaneous tract embolization is not advocated as the standard method of controlling hemorrhage because of possible injury to a renal artery after nephrostomy. Transcatheter arterial embolization should be considered immediately as an alternate treatment because of its safety and efficacy in acute settings in patients with arterial lesions after percutaneous renal surgery (5,8).

The present study has a small sample size, and the evaluation of long-term follow-up was insufficient. A longer follow-up period in a larger sample size would improve the evidence of efficacy of this new technique.

In conclusion, three cases of successful tract embolization by AACTE for arterial bleeding associated with PCN are reported. The AACTE technique is a safe and poten-