Clinical outcomes of secondary self-expandable metal stent (SEMS) insertion due to previous stent migration in malignant colorectal obstruction

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Directed by Professor Jae Hee Cheon

The Master's Thesis
submitted to the Department of Medicine,
the Graduate School of Yonsei University
in partial fulfillment of the requirements for the degree
of Master of Medical Science

A Ra Choi

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ABSTRACT

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INTRODUCTION: Self-expanding metal stents (SEMS) are widely used for the relief of malignant colorectal obstruction. Recent clinical studies have found that SEMS placement is relatively safe and effective, but reported long-term complication rates ranging from 25-50%. There has been only limited research concerning the clinical outcomes of secondary SEMS placement after previous stent migration. The aim of this study was to assess clinical outcomes following secondary SEMS after stent migration compared to those of secondary stent insertion due to causes other than migration.

METHODS: Self-expanding metal stents (SEMS) are widely used for the relief of malignant colorectal obstruction. Recent clinical studies have found that SEMS placement is relatively safe and effective, but reported long-term complication rates ranging from 25-50%. There has been only limited research concerning the clinical outcomes of secondary SEMS placement after previous stent migration. The aim of this study was to assess clinical outcomes following secondary SEMS after stent migration compared to those of secondary stent insertion due to causes other than migration.

RESULTS: The baseline clinical characteristics were similar between the two groups. The overall immediate technical and clinical success rates of secondary SEMS insertion in the migration and non-migration groups were 94.7% and 83.3% (p-value 0.09) and 73.7% and 53.3% (p-value 0.122), respectively. In the migration group, immediate clinical success was associated with a history of immediate clinical success (first

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stent insertion) and a longer time interval between the first and second stent insertion. The overall clinical success was higher when there was no problem with maintenance of stent patency after the first stent insertion. Other factors including stent type, stent length, etiology of obstruction, or degree of obstruction did not differ significantly between groups.

CONCLUSION: The success rate of secondary SEMS insertion following stent migration did not differ from that of secondary stent insertion due to other causes. The immediate and long-term clinical success rates following migration were dependent on the success of the first stent, suggesting that the success of the first procedure may be useful for selecting further treatment options, notably stent insertion versus surgical intervention.

Key words: colorectal obstruction, SEMS, clinical outcome

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I. INTRODUCTION

Self-expanding metal stent (SEMS) insertion has been established as a first-line option for achieving acute colonic decompression in obstructive colorectal cancers.[1-3] Therefore, patients who had been traditionally treated with an emergent surgical intervention now undergo SEMS insertion as a surgical alternative or bridging method.[3] Recent clinical studies have found that SEMS placement is not only relatively safe and effective,[4] but also improves quality of life, clinical outcomes, and is cost effective.[5,6] However, long-term complications of single SEMS insertion such as migration, obstruction, or perforation occur in 25-50% of cases.[7-12]

In practice, SEMS often become occluded by progressive tumor in-growth or outgrowth[5] and also migrate following a reduction in tumor size secondary to chemotherapy.[12] In cases of recurrent bowel-occluding colorectal cancers, treatment options include a secondary intervention by insertion of another SEMS through the previous stent (stent-in-stent) or surgical intervention. There

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have been a few reports of outcomes following secondary stent-in-stent SEMS insertion to alleviate initial stent obstruction due to cancer in-growth.[5] With regard to migration, covered stents may migrate more frequently, since anchorage of the stent by integration into the tumor and surrounding tissue occurs less often than with uncovered stents.[13] Other differences in stent design may also contribute to differences in the occurrence of stent migration.[14] The majority of migration cases are currently managed with the placement of a new stent.[1] However, there have been few studies examining the clinical outcomes and significance of secondary SEMS after previous stent migration in the context of malignant colorectal obstruction.

Thus, we sought to assess the clinical outcomes and prognosis of secondary SEMS placement after migration compared to those with secondary stent insertion due to causes other than migration. We also aimed to identify risk factors for long-term outcomes of secondary SEMS after initial stent migration, and to suggest criteria for selecting further treatment options.

II. MATERIALS AND METHODS:

Patients

This study was approved by the Institutional Review Board of Severance Hospital. Between Jan 2005 and Feb 2011, 422 total patients underwent SEMS insertion for malignant colorectal obstruction at Severance Hospital, Seoul, Korea. Of these, 98 patients underwent secondary SEMS, 38 of whom underwent secondary SEMS placement due to previous stent migration (migration group) while the remaining 60 patients underwent secondary SEMS for other causes such as repeat obstruction due to tumor in-growth. Patients who had benign indications for SEMS insertion were excluded.[15] Patient demographic and clinical data were retrospectively identified by reviewing an endoscopy database and clinical records.[5,16] Patients enrolled in this study were

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followed until their last clinic visit or death.

Obstruction was defined to be complete if the patients were unable to pass stool and gas and was considered to be incomplete if patients were symptomatic but able to pass gas or had paradoxical diarrhea.[17] Immediate clinical success was defined as clinical relief of obstructive symptoms immediately after stent insertion.[5] Immediate technical success was defined as stent placement with correct deployment and precise positioning at the location of the stenosis and was confirmed radiographically.[12] Delayed clinical success was defined as the maintenance of stent function without re-obstruction or migration requiring alteration of management for seven or more days.[7] Moreover, clinical failure was defined as the relapse or development of previous symptoms related to the obstruction or the occurrence of complications.[5,7,11]

The complications associated with SEMS were managed with endoscopical interventions such as placement of another SEMS or fluoroscopically-guided through the scope (TTS) balloon dilatation or surgical interventions. Colostomy was performed when an endoscopical approach failed.

Endoscopic details

SEMS placement was performed by one of eight endoscopists at Severance Hospital using SEMS techniques described in detail elsewhere.[18] A flexible colonoscope (CF-H260AI, Olympus, Tokyo, Japan) was used to approach the site of previous SEMS migration. A biliary guidewire (Jagwire, Boston Scientific, Natick, MA, USA) and catheter (ERCP-Catheter, MTW Endoskopie, Wesel, Germany) were used to replace the SEMS. Fluoroscopic guidance was achieved using oral contrast agents (Gastrografin, Scherring, West Sussex, UK).

Four types of SEMS were used: a covered Niti-s colonic stent (Taewoong Medical, Seoul, Korea), a covered Comvi sent (Taewoong Medical), an uncovered WallFlex colonic stent (Boston Scientific, Denver, CO, USA), and an

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uncovered Niti-s colonic D type stent (Taewoong Medical). The stent type was based on the preference or experience of each endoscopist, patient characteristics, and type of previously placed SEMS.

Statistical analysis

Categorical data were evaluated using the chi-square test and the Fisher's exact test. Continuous data were compared using the Mann-Whitney U test. Descriptive statistics for continuous variables are expressed as median (range) values. Survival was determined using Kaplan-Meier survival analysis and log-rank comparisons. A p-value < 0.05 was considered significant. Data were analyzed using SPSS 12.0 for Windows (SPSS Inc., Chicago, IL, USA).

III. RESULTS

Patient characteristics

Patient and pathologic characteristics in the migration and non-migration groups are presented in Table 1. The baseline clinical characteristics were similar between the two groups. The full study population comprised 63 males (64.3%) and the most common etiology for obstruction was primary colorectal cancer (intrinsic obstruction - 58 patients, 59.2%). Extrinsic compression including metastasis from malignancies other than colorectal cancer was present in 40 patients (40.8%). Sixty-six patients (67.3%) had complete obstruction. With regard to the location of the obstruction, 82 patients (83.7%) had a left-sided obstruction. Adenocarcinoma was confirmed in 72 patients (73.5%).

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Table 1. Baseline characteristics of patients that underwent secondary stent insertion between migration (n=38) and non-migration groups (n=60)

Characteristics	Total patients (N=98)	Migration group (N=38)	Non-migration group (N=60)	P-value
Sex, no				0.497
Male	63	26	37	
Female	35	12	23	
Age, years (range)	64.4 (27-87)	67.2 (36-87)	62.6 (27-85)	0.140
Etiology, no				0.524
Intrinsic	58	24	34	
Extrinsic	40	14	26	
Carcinomatosis, no				0.085
Yes	41	20	21	
No	57	18	39	
Degree of obstruction, no				0.112
Incomplete	32	16	16	
Complete	66	22	44	
Obstruction site, no				0.314
Left colon	82	30	52	
Right colon	16	8	8	
Pathology, no				0.969
Adenocarcinoma	72	28	44	
Others	26	10	16	

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Clinical outcomes and complication data

A flow diagram of patient outcomes following secondary SEMS insertion is shown in Figure 1. The median follow-up duration for the 98 patients who underwent SEMS placement was 308.2 (8-1395) days and the median survival time following secondary SEMS insertion was 197.1 (4-1385) days. Secondary SEMS were successfully inserted in 86 of 98 patients (87.8%). The median duration of secondary SEMS patency was 111 (1-1385) days as shown in Table 2. The immediate technical success rates of secondary SEMS insertion in the migration and non-migration groups were 94.7% (36/38) and 83.3% (50/60), respectively. Clinical success was achieved in 28 of the 38 patients (73.7%) in the migration group. Sixteen patients in the migration group (42.1%) showed improvement in their clinical symptoms as a result of sustained secondary stent patency, meeting criteria for long-term clinical success, while the other 22 patients (58.9%) did not. Ten of the twenty-two patients who had delayed clinical failure underwent surgery due to colonic perforation. The remaining 12 patients underwent additional SEMS insertion due to stent migration (4 patients), re-obstruction (5 patients), and other reasons (3 patients). Other reasons for SEMS insertion included stool impaction, extrinsic compression, and an intermittent obstructive pattern of symptoms due to a mass proximal to the previous stent location, which created a check valve phenomenon. Clinical success was achieved in 32 of the 60 patients (53.3%) in the non-migration group. Twenty-five patients in the non-migration group (41.7%) experienced long-term clinical success, with improvement in their clinical symptoms as a result of sustained secondary stent patency, while long-term clinical success was not achieved in the remaining 35 patients (58.9%).

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Figure 1. Diagram of patients with secondary SEMS insertion

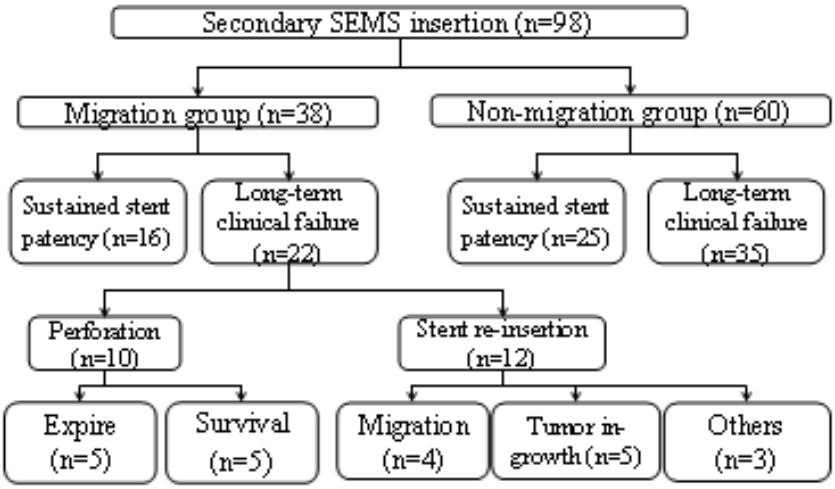

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Table 2. Comparison of clinical outcomes between migration and non-migration groups

	Total patients (N=98)	Migration group (N=38)	Non-migration group (N=60)	P-value
Immediate technical outcome, no				0.12*
Success	86	36	50	
Failure	12	2	10	
Immediate clinical outcome, no				0.122
Success	60	28	32	
Failure	38	10	28	
Long-term complications, no				0.634
No	41	16	25	
Yes	57	22	35	
Follow-up period, days	308.2	315.8	303.4	0.5
Median (range)	(8~1395)	(8~1299)	(20~1395)	
Survival after 2^{nd} insertion, days	197.1	178.9	208.6	0.816
Median (range)	(4~1385)	(4~641)	(7~1385)	
Stent patency duration after 2^{nd} insertion, days	111	122	82	0.754
Median (range)	(1~1385)	(4~641)	(1~1385)	

*Fisher's exact test

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Predictive factors of immediate and overall clinical success

Immediate clinical success of secondary SEMS insertion was associated with a history of clinical success at the first SEMS insertion (Table 3). The remaining variables, including patient sex, age, etiology of obstruction, obstruction site and degree, or a history of previous treatment were not significantly associated with immediate clinical success of secondary SEMS insertion. Moreover, stent variables such as the type of stent, direction of migration of the first stent, and duration between placement of the first and second stents did not affect the clinical outcomes. There was no significant difference in survival rates between the two groups (Figure 2). Moreover, the duration of patency after secondary SEMS insertion was not different between the two groups (Figure 3).

Predictive factors for long-term clinical success were identified using the Kaplan-Meier method and log–rank comparisons. Long-term clinical success after secondary SEMS in the migration group was associated with the absence of complications after insertion of the first stent (P-value < 0.01) and a longer time interval (more than 100 days) between the first and second stent insertion (P-value = 0.11) (Figure 4). Other factors such as the presence of carcinomatosis, degree of obstruction, site of obstruction, or direction of migration of the first stent were not significantly associated with long-term clinical success.

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Table 3. Comparison of predictive factors for immediate clinical success as a secondary intervention for migrated self-expandable metal stents (SEMS)

	Immediate clinical success (N=28)	Immediate clinical failure (N=10)	P-value
Sex, no			0.453*
Male	18	8	
Female	10	2	
Age, years (range)	66.1 (36~87)	70.1 (56~85)	0.404
Etiology, no			1.0*
Intrinsic	18	6	
Extrinsic	10	4	
Carcinomatosis, no			0.719*
Yes	14	4	
No	14	6	
Degree of obstruction, no			0.556
Incomplete	11	5	
Compete	17	5	
Obstruction site, no			0.082*
Left colon	20	10	
Right colon	8	0	
Pathology, no			0.404*
Adenocarcinoma	20	10	
Others	8	0	
Immediate clinical success of first stent, no			<0.001*
Yes	26	0	
No	2	10	
Immediate technical success of first stent, no			0.064*
Yes	28	8	

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No	0	2	
Delayed clinical success of first stent, no			0.719*
Yes	14	6	
No	14	4	
Previous treatment, no			0.694
None	8	4	
Chemotherapy	9	6	
Radiation therapy	1	0	
Duration between first and second	137.1	83.5	0.065
Stent (days)	(4~913)	(1~559)	
Direction to migration of first stent, no			0.124*
Distal	17	9	
Proximal	11	1	
Type of stent, no			0.699*
Covered	20	8	
Uncovered	8	2	
Combined balloon dilatation, no			1.0*
Without	26	10	
With	2	0	

*Fisher's exact test

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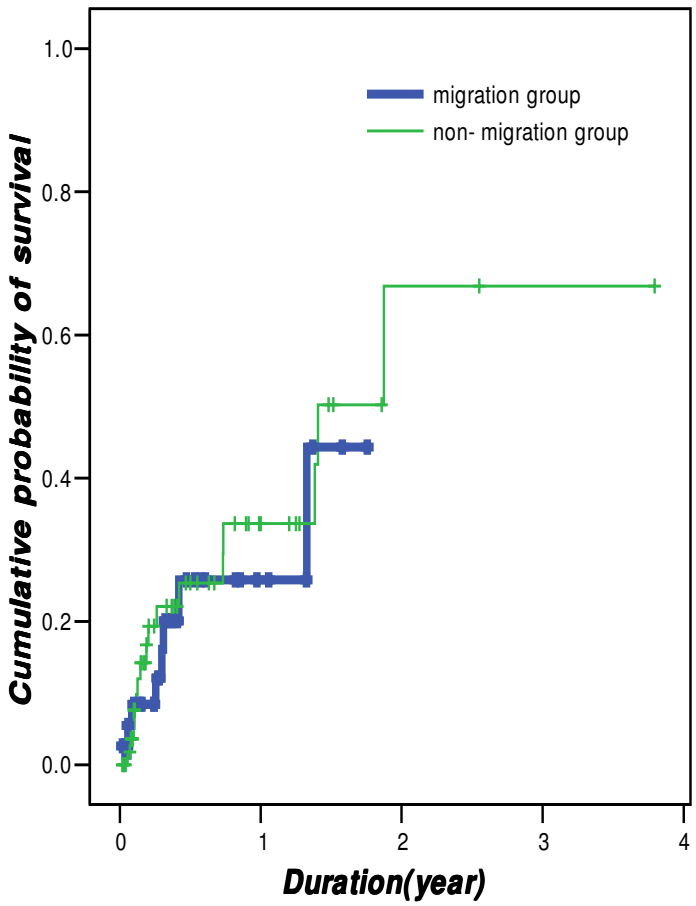
Figure 2. Kaplan-Meier curves of survival in patients who received secondary self-expandable metal stents (SEMS) intervention between migrated SEMS and non migrated SEMS groups



p-value=0.74

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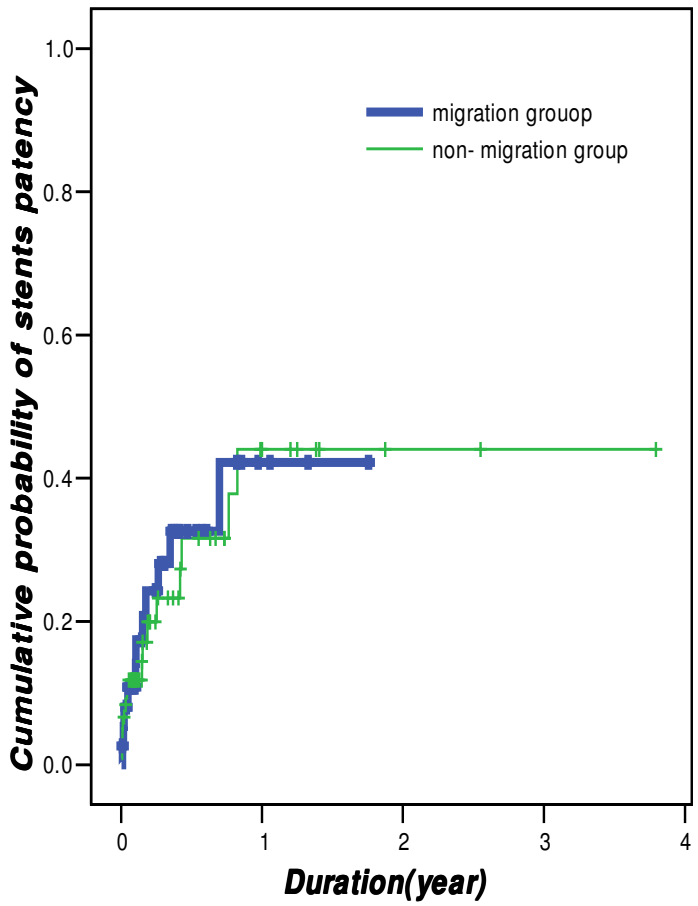
Figure 3. Kaplan-Meier curves of stents patency in patients who received secondary self-expandable metal stents (SEMS) intervention between migrated SEMS and non migrated SEMS groups



p-value=0.81

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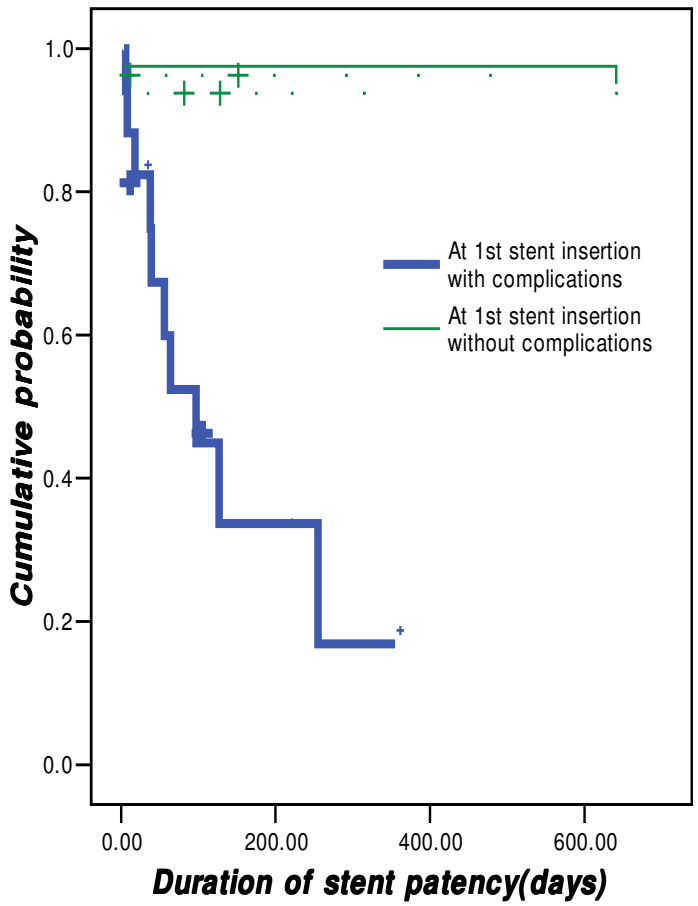
Figure 4. Kaplan-Meier curves of risk factors for long-term clinical success in patients who received secondary self-expandable metal stents (SEMS) intervention



p-value < 0.001

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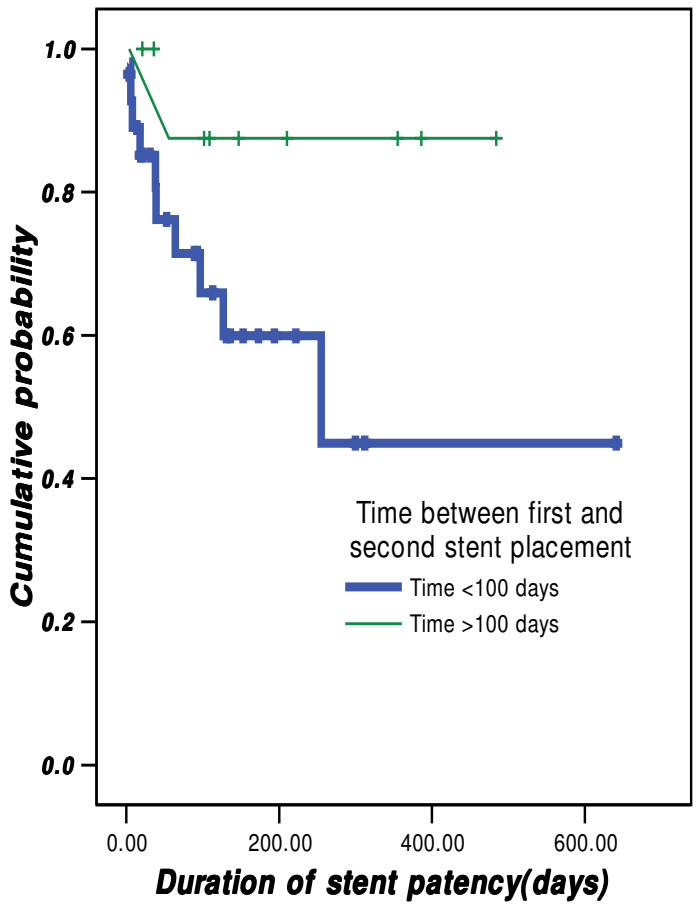

P-value=0.11

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IV. DISCUSSION

Recently, following the increasing rate of SEMS use, a growing body of evidence concerning the efficacy, safety, and clinical outcomes associated with SEMS has emerged.[7,15,19-21] Some studies have reported that placement of SEMS does not seem to be as effective as suggested because of a high rate of late complications.[12,20-24] Notably, however, discussions of the various issues associated with colorectal SEMS placement have only focused on the first SEMS placement.[7,15] In particular, although there are a few reports on proper management of occluded SEMS by stent-in-stent placement,[5] studies concerning secondary SEMS replacement after previous stent migration have not yet been published. To our knowledge, this is the first study focusing on the clinical outcomes of secondary SEMS insertion due to previous stent migration in malignant colorectal obstruction. We aimed to assess the immediate and long-term clinical outcomes of secondary SEMS placement after migration compared to those with secondary stent insertion due to causes other than migration and to identify factors predictive of prognosis.

In our study, migration of a previously successfully inserted stent occurred in 38 (9%) patients, which is consistent with the published median rate of migration (11%), although rates in the literature range from 0%-50%.[1,6,20,25] These variable rates are thought to be affected by differing levels of complexity involved in the procedures.[20] SEMS placement can be affected by variables such as the degree of obstruction, stent type used, and the endoscopist's level of experience.[7,26]

In our analysis, the overall immediate technical and clinical success rates of secondary SEMS were not significantly different between the migration and non-migration groups. Although we are cautious to generalize these results with a simple comparison between the migration and non-migration groups, we hypothesize that although the causes of re-obstruction themselves are not the

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significant factors affecting the clinical outcomes. The Kaplan-Meier survival analysis supported this notion, showing that there were no significant differences in immediate (Table 2) or long-term clinical outcomes with regard to survival and stent patency between the migrated and non-migrated SEMS groups (Figure 2, 3). These findings suggest that patients with a SEMS that migrated for any reason could undergo secondary SEMS.

Previous reports showed that the technical and clinical success rates of first stent placement varied from 46% to 100%.[1,27,28] Moreover, recent studies by Small et al.[7] and Foo et al.[29] indicated much higher rates of clinical success. However, there are relatively few data detailing the clinical outcomes of secondary SEMS insertion. Only one report investigated the outcomes of secondary stent-in-stent SEMS placement following tumor occlusion.[5] According to that study, secondary 'stent-in-stent' SEMS placement was effective, despite a slightly lower success rate compared with primary SEMS placement. Moreover, the only predictive factor of immediate clinical success of stent-in-stent placement was patency duration of the primary SEMS.[5] Our results were consistent with those findings, in that we found that immediate clinical success of secondary SEMS insertion was associated only with the history of clinical success of the first SEMS insertion. In other words, the immediate clinical success of stent insertion following migration was dependent on the success of the first stent. Our results suggest that it is appropriate to actively attempt to insert a secondary SEMS in cases that have migrated only after the successful insertion of the primary stent. However, if the first SEMS fails to immediately relieve obstructive symptoms or if there is a poor clinical outcome immediately after the primary stent insertion, further SEMS placement could be inappropriate. In those cases, it might be more desirable to consider surgical decompression rather than secondary SEMS insertion.

Also, based on an earlier report, the absence of carcinomatosis is an important factor in maintaining the long-term clinical success a stent-in-stent.[5]

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On the contrary, our study demonstrated that the long-term clinical success after secondary SEMS in the migration group was associated only with the absence of complications after insertion of the first stent and sustained stent patency for more than 100 days. Overall, in terms of long-term outcomes as well as immediate outcomes, the success or failure of the first stent placement appears to primarily predict the outcomes of the second stent. This may be clinically applicable for decision-making regarding placement of a secondary SEMS. Ultimately, if the first stent remains patent for a relatively long time without complication, then it would be better to insert secondary stent instead of performing surgical decompression.

Our study has several limitations associated with the retrospective nature of data collection and the single-center design. In the future, a prospective study to determine whether the factors affecting the outcome of secondary SEMS placement are concordant with factors affecting the first stent insertion is necessary to confirm our results.

V. CONCLUSION

Taken together, our results suggest that there is no difference in the success rate of secondary SEMS insertion following stent migration compared with secondary stent insertion due to other causes. The immediate and long-term clinical success rates following migration were dependent on the clinical success of the first stent, suggesting that the clinical success of the first stent may be a useful criterion for determining further treatment options, notably stent insertion versus surgical intervention.

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ABSTRACT(IN KOREAN)

악성 대장직장 폐쇄 환자에서 첫 번째 스텐트 이동에 의하여 재시행한 두 번째 SEMS의 임상 결과

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최아라

목적: Self-expanding metal stent (SEMS)는 악성 대장직장 폐쇄의 완화를 위하여 널리 사용된다. 최근 연구에서는 SEMS 삽입술은 비교적 안전하고 효율적인 시술이기는 하지만 25~50% 정도로 장기간의 합병증도 보고되고 있다. 하지만 두 번째로 시행한 SEMS에 대한 연구, 특히 첫 번째 스텐트의 이동에 의하여 재 시행한 경우에 관한 연구는 거의 없다. 이 연구의 목적은 첫 번째 스텐트 이동에 의하여 재시행한 SEMS의 임상적 결과를 그 외의 원인에 의하여 이동한 군과 비교하여 알아보는 것이다.

방법: 2005년 1월부터 2011년 2월까지 세브란스 병원에서 악성 대장직장 폐쇄로 SEMS 시행 받은 422명의 환자를 대상으로 하였고, 스텐트 이동에 의하여 재시행한 군과, 다른 원인에 의하여 재시행한 군의 임상 결과를 비교하였다. 또한 스텐트 이동에 의하여 재시행한 SEMS의 장기 예후를 알아 보았다.

결과: 두 군의 기본 임상 특성은 비슷하게 나타났다. 궁극적인 즉각적 기술적, 임상적 성공률은 이동 군과 비 이동 군간에 각각

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94.7%/83.3%(p-value 0.09) and 73.7%/53.3%(p-value 0.122)로 나타났다. 이동 군에서, 즉각적 임상 성공은 첫 번째 스텐트의 즉각적 임상 성공과 의미 있는 관련이 있었다. 결국, 첫 번째 스텐트 삽입술의 성공 여부에 따라서 두 번째 스텐트의 성적에 영향을 미치게 되며, 기타 다른 요인은 의미를 보이지 않았다.

결론:두 번째 SEMS의 임상 결과에 대하여 연구한 결과, 첫 번째 스텐트의 이동에 의하여 재시행한 경우도 두 번째 스텐트의 성적은 다른 원인에 의하여 재시행한 경우와 비교하여 다르지 않다.
즉, 이동 군에서 재시행한 스텐트의 단기, 장기 성적은 결국 첫 스텐트의 성공 여부와 관계가 높기 때문에 두 번째 스텐트 삽입 및 수술 여부를 결정할 때, 판단 기준이 될 수 있을 것으로 생각된다.

핵심되는 말 : 대장직장 폐쇄, SEMS, 임상 결과

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