Surefire Medical Clinical Data Presented - test 2

Jenna Clark <Jenna.Clark@surefiremedical.com> Thu, Jun 9, 2016 at
To: Jenna Clark <jennaclark70@gmail.com>

Dear Ms. Clark,

During the recent 2016 SIR Annual Scientific Meeting in Vancouver, the data from the attached abstract titled "Single Cent Experience with the Surefire Infusion System for Delivery of DEB-TACE in Treatment of HCC" was presented by Theresa M MD of Georgetown University Hospital.

In this retrospective study, the Surefire Infusion System achieved 83% objective response even in lesions that had previou failed DEB-TACE using standard end-hole catheters. According to the abstract, "SIS is a promising tool for delivery of DEB-' treatment of HCC and may lead to improved disease response compared to standard end-hole catheters."

Please see the complete summary of the study below or click here.

If you have any questions, please let me know. Thank you for your continued interested in Surefire Medical.

Best regards,

Jenna Clark

Marketing Manager

Surefire Medical, Inc.

6272 W. 91st Avenue

Westminster, CO 80031

303.717.2339

www.surefiremedical.com

Dear Dr. Arepally,

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CASE SERIES
Presented at the 2016 Society of Interventional Radiology Conference, Vancouver

Single Center Experience with the Surefire Infusion System for Delivery of DEB-TACE in Treatment of HCC

Alexander Y. Kim, MD[1], George E. Lynskey, MD[2], Theresa M. Caridi, MD[1], Donna C. Buckley, MD[3]
[1]Georgetown University Hospital, Washington, DC; [2]Georgetown University Hospital, Arlington, VA; [3]Gaithersburg, MD.

Purpose: To evaluate the efficacy of the Surefire Infusion System (SIS) for delivery of DEB-TACE in treatment of HCC.

Materials and Methods: A retrospective review was performed of all patients who underwent DEB-TACE for the treatment of HCC with the SIS in a 12-month period. All patients underwent standard angiogram to identify lesions, and treated with 100μm hydrogel microspheres + 50mg Doxorubicin. Treatment location was chosen to be as selective as possible. Patient outcomes were assessed based on mRECIST criteria on follow up imaging.

Results: 11 patients with 25 separate HCC lesions (mean size, 3.8cm) underwent DEB-TACE treatments using SIS. Of the 24 lesions that were treated with SIS, 12 were de-novo lesions and 12 had previously failed to respond to DEB-TACE using a standard end-hole catheter. With SIS, 15 of 24 (62.5%) of the lesions had complete response (CR), 5 of 24 (20.8%) demonstrated partial response (PR), and 4 lesion had stable disease (SD). Six lesions that did not achieve CR in the first treatment were re-treated with the SIS. Of these, 5 (83.3%) achieved CR. No hepatoxicity was observed; and four patients were successfully downstaged to within Milan criteria.

Conclusion: SIS is a promising tool for delivery of DEB-TACE in treatment of HCC and may lead to improved disease response compared to standard end-hole catheters. In this retrospective study, SIS achieved 83% OR even in lesions that have previously failed DEB-TACE using standard end-hole catheters. A larger, prospective trial is planned to further validate these findings.

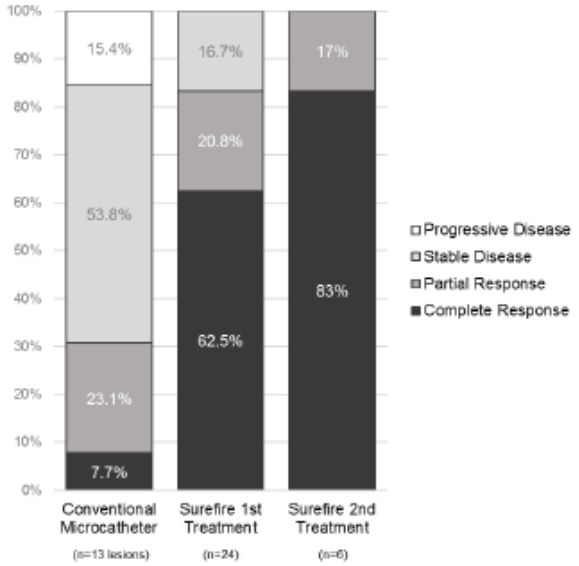
Table 1. Patient Characteristics

Characteristic	No. Patients (n=11)
Age (y)	59.5 (range, 36-74)
Sex (M:F)	10:1
Etiology of Liver Disease	
Hepatitis B	3 (27.3%)
Hepatitis C	5 (45.5%)
Alcoholic hepatitis	2 (18.2%)
Nonalcoholic steatohepatitis	1 (9.1%)
Child-Pugh Classification	
A	9 (81.8%)
B	2 (18.2%)
Tumor Distribution	
Unilobar	6 (54.4%)
Bilobar	5 (45.5%)
BCLC Stage	
A	4 (36.4%)
B	7 (63.6%)

Table 2. Lesion Characteristics

Characteristic	No. Lesions (n=25)
Avg. no of lesion	2.5 (range, 1—6)
Lesion size prior to DEB-TACE (cm)	3.8 (range, 1.6—9.0)
Viable lesion size prior to First ARM TACE (cm)	3.6 (range, 0.8—9.0)

Figure 1. Tumor Response at Follow-up



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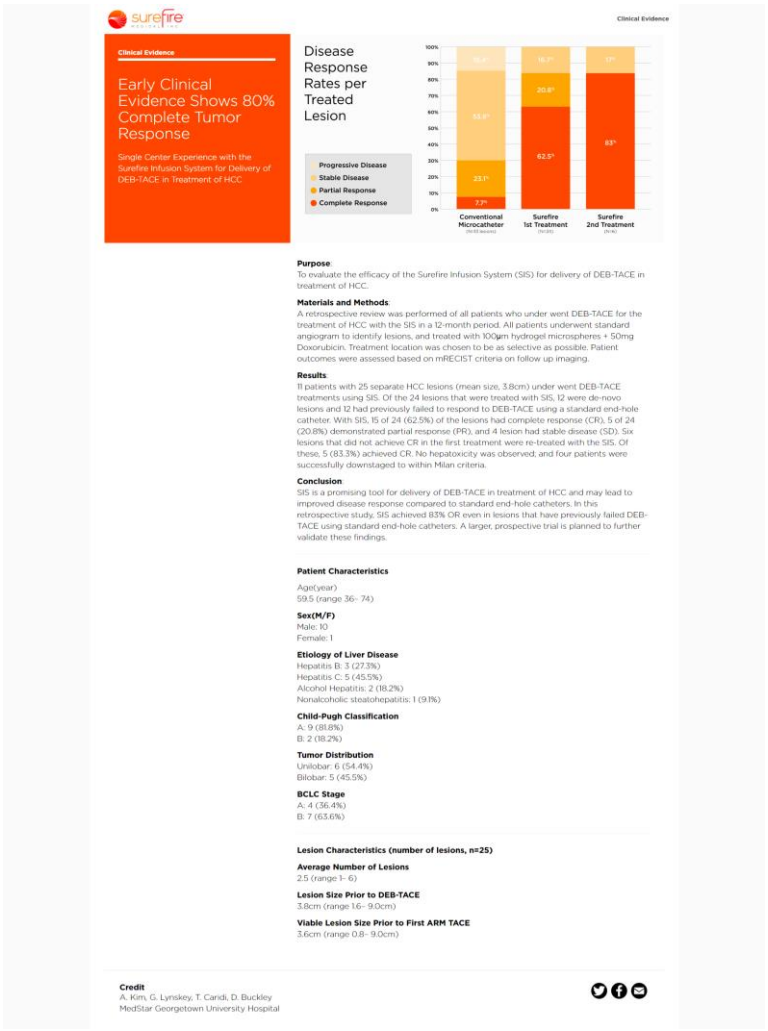

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Clinical Evidence

Clinical Evidence

Early Clinical Evidence Shows 80% Complete Tumor Response

Single Center Experience with the Surefire Infusion System for Delivery of DEB-TACE in Treatment of HCC

Disease Response Rates per Treated Lesion

Purpose
To evaluate the efficacy of the Surefire Infusion System (SIS) for delivery of DEB-TACE in treatment of HCC.

Materials and Methods
A retrospective review was performed of all patients who under went DEB-TACE for the treatment of HCC with the SIS in a 12-month period. All patients underwent standard angiogram to identify lesions, and treated with 100µm hydrogel microspheres + 50mg Doxorubicin. Treatment location was chosen to be as selective as possible. Patient outcomes were assessed based on mRECIST criteria on follow up imaging.

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Conclusion
SIS is a promising tool for delivery of DEB-TACE in treatment of HCC and may lead to improved disease response compared to standard end-hole catheters. In this retrospective study, SIS achieved 83% OR even in lesions that have previously failed DEB-TACE using standard end-hole catheters. A larger, prospective trial is planned to further validate these findings.

Patient Characteristics

Age(year)
59.5 (range 36- 74)

Sex(M/F)
Male: 10
Female: 1

Etiology of Liver Disease
Hepatitis B: 3 (27.3%)
Hepatitis C: 5 (45.5%)
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Tumor Distribution
Unilobar: 6 (54.4%)
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BCLC Stage
A: 4 (36.4%)
B: 7 (63.6%)

Lesion Characteristics (number of lesions, n=25)

Average Number of Lesions
2.5 (range 1- 6)

Lesion Size Prior to DEB-TACE
3.8cm (range 1.6- 9.0cm)

Viable Lesion Size Prior to First ARM TACE
3.6cm (range 0.8- 9.0cm)

Credit
A. Kim, G. Lynskey, T. Caridi, D. Buckley
MedStar Georgetown University Hospital