Feasibility study of oral cooling system (Cooral®) for oral mucositis in patients receiving chemotherapy

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【Introduction】

Oral mucositis (OM) as adverse event of chemotherapy often worsen quality of life of patients receiving chemotherapy. Oral cooling system (Cooral® BrainCool AB) , which decrease the temperature of inside of mouth, may palliate oral mucositis. We evaluated the feasibility of Cooral® for oral mucositis in patients receiving chemotherapy.

【Methods】

Eligible Criteria

- 20 years of age or older
- Solid tumor
- Received alkylating agents, platinum, anthracycline, antimetabolite, or taxanes
- Out patients
- Provided written informed consent

Exclusion criteria

- Any oral disease
- Not able to apply the mouth device
- Oral cancer
- Received prior radiotherapy for oral cavity

Procedure

Patients apply Cooral® by him/herself. Cooling begins 30 minutes before the start of chemotherapy and continues until 30 minutes after finish of chemotherapy. During use of Cooral® , if necessary, patients can interrupt Cooral® for up to ten minutes.

Assessments

- Tolerability of Cooral (Number of patients who cannot apply or discontinue Cooral® , time from applying of Cooral® to take out it 30 minutes after chemotherapy finished, number of interruptions during use of Cooral®)
- Oral mucositis grade according to NCI-CTCAE
- Rating of oral pain measured with Numerical Rating Scale
- Patient reported impression using Cooral®

【Results】

All 6 patients completed the planned protocol.

Table.1 Patients Characteristics (N=6)

Median age - year (range)	55 (52-71)
Male sex – no. (%)	1 (17)
Previous chemotherapy - no. (%)	6 (100)
Previous alkylating agents, platinum, anthracycline, antimetabolite, or taxanes – no. (%)	6 (100)
Periodontal disease was in most recent one month – no. (%)	2 (34)
Received dentistry for most recent one month – no. (%)	1 (17)
Median times of toothbrushing per day - no. (range)	2 (2-3)
Smoking	0
Dry mouth - no. (%)	1 (17)
Regimens - no.	
FOLFIRI (Irinotecan + Fluorouracil) + Panitumumab	1
TC (Paclitaxel + Carboplatin)	1
Paclitaxel + Bevacizumab	1
TC (Docetaxel + Cyclophosphamide)	1
GC (Gemcitabine + Cisplatin)	1
AP (Doxorubicine + Cisplatin)	1

Table.2 Tolerability of Cooral® (N=6)

Number of patients who use Cooral® for planed full time		
yes	6	
no	0	
Median time from applying of Cooral® to take out it - min. (range)	212.5 (125-270)	
Number of interruptions during use of Cooral®		
0~1	1	
2~3	2	
4~5	3	
6~	0	

Table.3 Assessment of mucositis and oral pain (N=6)

Grade of oral mucositis (NCI-CTCAE)		
1	5	
2	0	
3	0	
4	0	
blank	1	
NRS (0 to 10)		
0~1	5	
2~5	0	
6~10	0	
blank	1	

Questionnaire about Cooral™ cooling

4. Was it unpleasant to have Cooral™ in your mouth?

☐ No, not at all (skip to question 6)

☐ No, hardly at all

☐ Yes, a little

☐ Yes, very much so

5. If you experienced some form of discomfort, in what way was it unpleasant? (several alternatives may be chosen)

A ☐ I got cold

B ☐ I became numb

C ☐ It tasted bad

D ☐ I got a headache

E ☐ Shooting pains in my teeth

F ☐ My mouth got sore

G ☐ Poor fit

H ☐ I felt nauseous

J ☐ It was difficult to swallow

K ☐ It chafed

L ☐ Other.....

Figure.1 Impression of use from questionnaire (N=6)

Q. Was it unpleasant to have Cooral® in your mouth?

【Conclusion】

- According to the preliminary results of 6 patients, no patients discontinue the Cooral® system.
- The mucositis and oral pain were almost mild.
- The form of mouthpiece needs to be improved for better fit.
- Further evaluation is needed.

This trial is registered on UMIN (identifier : UMIN000034478)

【References】

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