厚生労働科学研究費補助金(医療機器開発推進研究事業)
分担研究報告書

レーザー消化管内視鏡治療装置の開発に関する研究

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研究要旨

早期消化管がん治療に有効な内視鏡的粘膜下層剥離術(ESD)において、従来の高周波電気メスに代わる炭酸ガスレーザーを用いたレーザーESD 装置開発のための、前臨床試験及び臨床研究の計画支援を行った。開発機器システムの構成の評価、in vitro、in vivo 実験による安全性、有効性の検証方法の計画支援を行い、今年度は、2 度目の PMDA 薬事戦略事前相談に持ち込むことが出来た。

A．研究目的

早期消化管がん治療に有効な内視鏡的粘膜下層剥離術(ESD)において、従来の高周波電気メスに代わる炭酸ガスレーザーを用いたレーザーESD 装置開発のための、前臨床試験及び臨床研究計画を支援することを目的とした。

B．研究方法

開発機器システムの構成の評価を行った。また、ブタ切除胃を用いた in vitro、及び生体ブタを用いた in vivo 実験による安全性、有効性の検証方法を検討した。

PMDA の 2 度目の薬事戦略事前相談に向けて、システム構成、ハードウエアの評価状況、in vitro、in vivo 実験による安全性、有効性を整理した。

（倫理面への配慮）

本課題で行う、生体ブタを用いる前臨床試験に対しては、動物実験委員会で審議、承認の上、実験動物に対する動物愛護に対して十分配慮した。

C．研究結果

ESD にレーザを使うというところが明らかに既存製品と異なり、この部分は新規事項であり、臨床試験無しというわけにはいかないと考えられた。動物実験のみで、臨床不要と主張する場合は、動物実験でその根拠が明確でなければならない。今年度、PMDA の 2 度目の薬事戦略事前相談を受け、対面相談に向けての安全性・有効性について、以下の事項が明らかになった。

- ファイバーと曲げ強度、柔軟性がどの程度保証できるのか、内視鏡側で屈曲制限を加えて使うとかの形にすることもありえる。
- 動物での評価で基本的に十分と考えているようだが、その根拠となる説明が必要。人での試験については、治験とはいかなくとも臨床試験は必要である。
- 電気メスの経験があってもレーザのト

レーニングは必要と思う。どのようなトレーニングが必要かは、説明する必要がある。

D．考察

これまでの結果で、開発品のスペックがほぼ決定した。来年度は、in vitro、in vivo 安全性を検証した上で、PMDA の対面相談を受け、臨床試験の規模を決定し、臨床試験計画を作成する。

E．結論

来年度は、最終システム構成を決定し、in vitro、in vivo 安全性を検証した上で、PMDA 薬事対面相談を受け、臨床試験計画を作成する。

F．健康危険情報

なし。

G．研究発表

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H．知的財産権の出願・登録状況
（予定を含む。）

1. **特許取得**

なし。

2. **実用新案登録**

なし。

3.**その他**

なし。