Package 'idem'

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Title Inference in Randomized Controlled Trials with Death and Missingness

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Description In randomized studies involving severely ill patients, functional outcomes are often unobserved due to missed clinic visits, premature withdrawal or death. It is well known that if these unobserved functional outcomes are not handled properly, biased treatment comparisons can be produced. In this package, we implement a procedure for comparing treatments that is based on the composite endpoint of both the functional outcome and survival. The procedure was proposed in Wang et al. (2016) <DOI:10.1111/biom.12594> and Wang et al. (2020) <DOI:10.18637/jss.v093.i12>. It considers missing data imputation with different sensitivity analysis strategies to handle the unobserved functional outcomes not due to

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idem-package

Inference in Randomized Clinical Trials with Death and Missingness

Description

This package contains the functions for drawing inference in randomized clinical trials with death and intermittent missingness.

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Notation

Consider a two-arm randomized study. Let Y_k denote outcome measured at time t_k and Z denote a functional endpoint that is a function of Y. Let L denote the survival time. Let X denote the baseline covariates and T denote the treatment assignment.

Ranking

If two subject were both alive at the end of the study, they are ranked based on functional outcome Z. If at least one subject was dead at the end of the study, they are ranked based on survival time L.

Treatment effect, θ is defined as the probability that the outcome for a random individual randomized to treatment T=0 is less than the outcome of a random individual randomized to treatment T=1 minus the probability that the outcome for a random individual randomized to treatment T=0 is greater than the outcome of a random individual randomized to treatment T=1.

Missingness

In order to estimate θ in the presence of missing data, we need to impute Z for subjects alive at the end of the study with Y_k missing for some k.

The benchmark assumption we consider for the imputation is the complete case missing value (CCMV) restrictions. We then consider exponential tilting models for introducing sensitivity parameters for evaluating the robustness of the findings with regards to different missing data mechanism assumptions. The models are as follows:

$$f(Y_{mis}^{(s)}|Y_{obs}^{(s)}, Y_0, X, T, S = s) \propto \exp(\beta_T Z) f(Y_{mis}^{(s)}|Y_{obs}^{(s)}, Y_0, X, T, S = 1)$$

where S denotes the missingness patterns, S=1 denotes the completers and β_T denotes the sensitivity parameter for arm T.

Graphical user interface (GUI)

This package provides a web-based GUI. See imShiny for details.

References

Wang C, Scharfstein DO, Colantuoni E, Girard T, Yan Y (2016). Inference in Randomized Trials with Death and Missingness. < DOI:10.1111/biom.12594>

Wang C, Colantuoni E, Leroux A, Scharfstein DO (2020). idem: An R Package for Inferences in Clinical Trials with Death and Missingness. <DOI:10.18637/jss.v093.i12>

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abc

Example dataset

Description

The Awakening and Breathing Controlled (ABC) trial randomized critically ill patients receiving mechanical ventilation 1:1 within each study site to management with a paired sedation plus ventilator weaning protocol involving daily interruption of sedative through spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs) or sedation per usual care (UC) and SBTs.

The example dataset is from a single site substudy in ABC. The researchers assessed differences in cognitive, psychological and functional outcomes at 3 and 12 months after randomization.

Format

A dataframe with 5 variables:

AGE Age

TRT Treatment assignment. 0: UC + SBT, 1: SAT + SBT

SURV Survival days

Y2 Cognitive score at 12 months

Y1 Cognitive score at 3 months

References

T. D. Girard, J. P. Kress, B. D. Fuchs, J. W. W. Thomason, W. D. Schweickert, B. T. Pun, D. B. Taichman, J. G. Dunn, A. S. Pohlman, P. A. Kinniry, J. C. Jackson, A. E. Canonico, R. W. Light, A. K. Shintani, J. L. Thompson, S. M. Gordon, J. B. Hall, R. S. Dittus, G. R. Bernard, and E. W. Ely. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (awakening and breathing controlled trial): a randomised controlled trial. Lancet, 371:126-134, 2008.

imData

Create data for IDEM analysis

Description

Create a class IDEMDATA object for IDEM analysis

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Usage

```
imData(
   data,
   trt = NULL,
   surv = NULL,
   outcome = NULL,
   endfml = NULL,
   y0 = NULL,
   cov = NULL,
   duration = 9999,
   bounds = NULL,
   trt.label = NULL,
   unitTime = "days",
   err.terminate = TRUE,
   ...
)
```

Arguments

data	Original dataset
trt	Variable name for the Control (0) and Intervention (1) treatment assignments in the dataset
surv	Variable name for the survival (time to event) variable in the dataset
outcome	Chronologically ordered vector of variable names for clinical outcomes in the dataset excluding baseline
endfml	R expression indicating the user-specified final outcome of interest. This is the function for Z of one or more of Y_k 's
y0	Variable name of the baseline clinical outcome
cov	Vector of variable names for the covariates used in the imputation procedure for missing clinical outcomes
duration	Length of the study. This is the time at which subjects' are assumed to be censored
bounds	Numeric vector of lower and upper bounds for subjects' imputed clinical outcomes
trt.label	label of the treatment arms
unitTime	Unit of time measurement for survival and function outcome time points
err.terminate	When there is error in the specification, the program should be stopped with an error message if err.terminate is true. Otherwise, the error message will be returned and the program will continue.
• • •	Additional specifications

Details

When there are errors in the specification, i.e. trt is not a column of data, a class IDEMERROR object will be returned. The detailed errors can be checked by calling print of the IDEMERROR object.

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Value

When the specifications are correct, a class IDEMDATA list will be returned. The list contains

```
data Original dataset
```

lst.var List of the specifications

Examples

imFitModel

Imputation model fitting

Description

Fit linear imputation models to the observed data from complete survivors for each treatment arm at each time point

Usage

```
imFitModel(im.data)
```

Arguments

im.data

A class IDEMDATA object generated by imData

Value

A class IDEMFIT list of modeling fitting results with the following items

im.data Original class IDEMDATA object

rst.mdl A list of modeling fitting results for each model with

lm results from function 1m

formula model formula

coef model coefficients

res residuals

h bandwidth of residuals for kernel density estimation

See Also

```
imData, idem-package
```

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Examples

imImpAll

Impute missing data

Description

Conduct imputation under benchmark assumptions or for sensitivity analysis for a given set of subjects using the model fitting results

Usage

```
imImpAll(
  fit.rst,
  data.all = NULL,
  deltas = 0,
  normal = TRUE,
  n.imp = 5,
  endponly = TRUE,
  update.progress = NULL,
  imputeNone = FALSE,
  ...,
  seed = NULL
)
```

Arguments

fit.rst	A class IDEMFIT results generated by imFitModel.
data.all	A dataframe containing subjects with missing data. The default value is NULL, in which case the function will impute missing data for subjects in the original dataset in the class IDEMFIT object fit.rst
deltas	Vector of imputation sensitivity parameters
normal	Logical variable indicating whether normality assumption should be made for the residuals
n.imp	Number of complete datasets required
endponly	Logical variable that indicates whether clinical outcomes not used in calculating the functional outcome are considered as missing and should be imputed. The default is FALSE, indicating that all missing clinical outcomes will be imputed sequentially

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update.progress

Parameter reserved for run idem in GUI mode

imputeNone If TRUE, no imputation will be conducted. The data from subjects that do not

need imputation will be returned

... options to call STAN sampling. These options include chains, iter, warmup,

thin, algorithm. See rstan::sampling for details.

seed Random seed

Value

If imputeNone is TRUE, return a dataset with the original data for the subset of subjects who died at the end of the study or had no missing outcomes.

Otherwise, return a class IDEMIMP list with components

lst.var List of parameters

complete A dataset with the original data for the subset of subjects who died at the end of the study or had no missing outcomes and the n.imp imputed missing outcomes for subjects who need missing value imputation.

n.imp Number of imputed complete datasets

deltas Imputation sensitivity parameters

org.data Original dataset

normal Normal assumption for the imputation

stan.par STAN options

Examples

imImpAll_mice

Impute missing data by mice

Description

Conduct imputation using the NARFCS model implemented in the mice package

imImpAll_mice 9

Usage

```
imImpAll_mice(
  im.data,
  deltas = 0,
  n.imp = 5,
  endponly = TRUE,
  seed = NULL,
  ...
)
```

Arguments

im.data A class IDEMDATA object generated by imData

deltas Vector of imputation sensitivity parameters

n.imp Number of complete datasets required

endponly Logical variable that indicates whether clinical outcomes not used in calculating the functional outcome are considered as missing and should be imputed. The default is FALSE, indicating that all missing clinical outcomes will be imputed sequentially

seed Random seed

Parameters for mice

Value

A class IDEMIMP list with components

lst.var List of parameters

complete A dataset with the original data for the subset of subjects who died at the end of the study or had no missing outcomes and the n.imp imputed missing outcomes for subjects who need missing value imputation.

n.imp Number of imputed complete datasets

deltas Imputation sensitivity parameters

org.data Original dataset

Examples

imImpSingle

imImpSingle

Impute missing data for MCMC convergence checking

Description

Call STAN model to impute missing data for an individual subject under benchmark assumption for MCMC convergence checking

Usage

```
imImpSingle(
  dsub,
  fit.rst,
  normal = TRUE,
  chains = 4,
  iter = 5000,
  warmup = 1000,
  control = list(adapt_delta = 0.95),
  ...,
  seed = NULL
)
```

Arguments

dsub	original individual subject data
fit.rst	A class IDEMFIT results generated by imFitModel.
normal	Logical variable indicating whether normality assumption should be made for the residuals
chains	STAN parameter. Number of Markov chainsm
iter	STAN parameter. Number of iterations
warmup	STAN parameter. Number of burnin.
control	STAN parameter. See rstan::stan for details.
• • •	other options to call STAN sampling such as thin, algorithm. See \mbox{rstan} : sampling for details.
seed	Random seed

Value

NULL if there is no missing data in dsub

Otherwise, return a class IDEMSINGLE object that contains a list with components

dsub original data of the subject

```
rst.stan A stan.fit class result returned from rstan::sampling complete A dataframe with complete data for the selected subject
```

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Examples

imInfer

Treatment effect estimation and hypothesis testing

Description

Estimate treatment effect size. Estimate variation and conduct hypothesis testing by bootstrap analysis.

Usage

```
imInfer(
  imp.rst,
  n.boot = 0,
  n.cores = 1,
  update.progress = NULL,
  effect.quantiles = c(0.25, 0.5, 0.75),
  quant.ci = c(0.025, 0.975),
  ...,
  seed = NULL
)
```

Arguments

imp.rst A class IDEMIMP object returned from imImpAll n.boot Number of bootstrap samples Number of cores for parallel computation. Fixed at 1 for Windows. n.cores update.progress Parameter reserved for run idem in GUI mode effect.quantiles Composite quantiles of interest for measuring treatment effect quant.ci Quantiles for extracting bootstrap confidence intervals Extra options for ranking subjects using the composite endpoint that include • cut.z: Clinically meaningful difference in the functional outcome • cut.surv: Clinically meaningful difference in survival time Random seed seed

imInfer

Details

If n.boot=0, bootstrap analysis will not be conducted. Instead, only the treatment effect size will be estimated using the imputed data.

Value

A class IDEMTEST list containing

Ist.var List of specification parameters

deltas Vector of sensitivity parameters

theta A data frame with columns

- Delta0: Sensitivity parameter for control arm
- Delta1: Sensitivity parameter for intervention arm
- Theta: Estimated θ
- SD: Standard deviation (when n.boot >0)
- PValue: p-value (when n.boot >0

effect.quantiles A data frame with columns

- Delta:Sensitivity parameter
- TRT:Treatment arm
- Q: Quantiles of the composite endpoint to be estimated
- QuantY: Estimated quantiles if the quantiles correspond to functional outcome (when n.boot >0)
- QuantSurv: Estimated quantiles if the quantiles correspond to survival days (when n. boot >0)
- Q: Boostrap quantiles for the QuantY (when n.boot >0)
- QSurv: Boostrap quantiles for the QuantSurv (when n.boot >0)

bootstrap A list with length n.boot. The *i*th item is the class IDEMEST list corresponding to the *i*th bootstrap sample

Examples

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imShiny

Run Web-Based idem application

Description

Call Shiny to run idem as a web-based application.

Usage

```
imShiny()
```

Details

A web browser will be brought up for users to access the GUI of idem.

Examples

```
## Not run:
run.idem()
## End(Not run)
```

plot.IDEMDATA

Plot of IDEMDATA object

Description

Generate different types of plots for class IDEMDATA objects.

Usage

```
## S3 method for class 'IDEMDATA'
plot(
    x,
    opt = c("survivor", "missing", "KM"),
    cols = c("black", "blue"),
    fname = NULL,
    ...
)
```

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Arguments

x A class IDEMDATA object generated by imData

opt Types of the plot

• survivor: Spaghetti plot for subjects alive at the end of the study

• missing: Plot the missing patterns of the observed data

• KM: Plot Kaplan-Meier survival curves

cols Curve colors of the treatment and control arm for survival plot or colors of the observed and missing data for missingness plot.

fname File name of the result pdf file. If fname is null, result pdf file will not be generated

See Also

imData

Examples

Extra arguments for plot

plot.IDEMFIT

Plot model fitting results

Description

Plot method of the class IDEMFIT to generate model fitting diagnosis plots

Usage

```
## S3 method for class 'IDEMFIT'
plot(x, trt = NULL, mfrow = NULL, ...)
```

Arguments

x	A class IDEMFIT object generated by imFitModel
trt	Treatment arm selected for the diagnostic plots. If NULL, all treatment arms are included
mfrow	Plot option
	Additional arguments

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See Also

```
imFitModel
```

Examples

plot.IDEMIMP

Plot imputation results

Description

Generate different types of plots for class IDEMIMP objects generated by imImpAll

Usage

```
## S3 method for class 'IDEMIMP'
plot(x, opt = c("imputed", "composite"), fname = NULL, ...)
```

Arguments

x A class IDEMIMP object returned from imImpAll

opt Types of the plot

- imputed: Plot density of imputed values and the density of the observed outcomes
- composite: Generate cumulative plot of the composite survival and functional outcome

fname File name of the result pdf file. If fname is null, result pdf file will not be generated

.. Options for generating the plots.

type = imputed

- deltas: Imputation sensitivity parameter for which to generate the results
- endp: If TRUE, plot the densities of the imputed functional outcomes. Otherwise, plot the densities of the imputed outcomes
- adjdensity estimation option
- colsplot option for colors
- ltysplot options for line types
- xlimplot options

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- ylimplot options
- mfrowplot options

type = composite

- at.surv: Sets the range of the survival times to plot in the cumulative distribution function. By default the range is the range of survival values up to the duration of the study
- at.z: Sets the range of the functional outcome to plot in the cumulative distribution function. By defualt this is the range of the functional outcomes plus the buffer amount to improve visibility in the transition from survival to functional outcome
- p. death: Proportion of the plot width devoted to Survival. By default the cumulative distribution will devote horizontal space to the survival portion that is proportional to the number of subjects who die prior to duration
- buffer: Small horizontal gap used to better visually distinguish the transition from survival to functional outcome
- delta: Imputation sensitivity parameter for which to generate the results
- seg.lab: Labels for the two components of the composite outcome
- main: plot options

See Also

imImpAll

Examples

plot.IDEMINFER

Plot hypothesis testing results

Description

Generate contour plot of p-values or treatment effect theta for sensitivity analysis results

plot.IDEMSINGLE 17

Usage

```
## S3 method for class 'IDEMINFER'
plot(x, con.v = 0.05, nlevels = 30, opt = c("pvalue", "effect"), ...)
```

Arguments

X	A class IDEMINFER list generated by imInfer
con.v	Levels of contour plot
nlevels	Levels of color scale
opt	contour plots of pvalue or effect
	Options for filled.contour

Details

The plot will only be generated when bootstrap analysis has been conducted.

Examples

plot.IDEMSINGLE

Plot MCMC mixing results

Description

Plot method of the class IDEMSINGLE to generate traceplot of the imputed missing outcomes

Usage

```
## S3 method for class 'IDEMSINGLE' plot(x, ...)
```

Arguments

```
x A class IDEMSINGLE object returned from imImpSingle
... Additional arguments
```

See Also

```
imImpSingle
```

Examples

plot.summary.IDEMINFER

Plot survivors only and SACE analysis results

Description

Generate a plot of survivor only and survivor average causal effect values

Usage

```
## $3 method for class 'summary.IDEMINFER'
plot(
    x,
    opt = c("pvalue", "effect"),
    by.sace = TRUE,
    delta0 = 0,
    delta1 = 0,
    sace.delta = NULL,
    ...
)
```

Arguments

x	A class summary. IDEMSACE object generated by summary of IDEMINFER
opt	contour plots of pvalue or effect
by.sace	Logical value. If True, create a contour plot for given SACE sensitivity parameter. Otherwise, create a plot for treatment effect for given imputation sensitivity parameters
delta0	Selected treatment arm 0 sensitivity parameters
delta1	Selected treatment arm 1 sensitivity parameters
sace.delta	Single SACE sensitivity parameter
	Options for plot

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Details

The plot function will only generate the contour plot of p-values or treatment effects on functional outcomes for survivors only analyses.

For SACE analysis, the plot function generates contour plot of line plot based on the value of by.sace.

Examples

print.IDEMDATA

Print IDEMDATA object

Description

Print the specification details of class IDEMDATA objects generated by imData

Usage

```
## S3 method for class 'IDEMDATA'
print(x, ...)
```

Arguments

x A class IDEMDATA object generated by imData

... Additional arguments

See Also

imData

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print.IDEMERROR

Print error messages

Description

Print error messages in the parameter specifications generated by imData

Usage

```
## S3 method for class 'IDEMERROR'
print(x, html = FALSE, ...)
```

Arguments

x A class IDEMERROR object returned by imData when there are misspecifications

html Logical indicator for the format of the error messages. When TRUE, the error

messages are formatted in HTML format

... Additional arguments

See Also

imData

Examples

print.IDEMFIT

Print model fitting results

Description

Print method of the class IDEMFIT generated by imFitModel

Usage

```
## S3 method for class 'IDEMFIT'
print(x, ...)
```

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Arguments

x A class IDEMFIT object generated by imFitModel

... Additional arguments

Details

Print the results from 1m for all the models

See Also

```
imFitModel
```

print.IDEMIMP

Print imputation results

Description

Print method for class IDEMIMP objects generated by imImpAll

Usage

```
## S3 method for class 'IDEMIMP'
print(x, ...)
```

Arguments

x A class IDEMIMP object returned from imImpAll

... Extra arguments

See Also

imImpAll

print.IDEMINFER

Print inference results

Description

Print method of class IDEMINFER for treatment effect estimation and hypothesis testing results

Usage

```
## S3 method for class 'IDEMINFER'
print(x, delta0 = NULL, delta1 = NULL, ...)
```

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Arguments

X	A class IDEMINFER list generated by imInfer
delta0	Selected treatment arm 0 sensitivity parameters
delta1	Selected treatment arm 1 sensitivity parameters
• • •	Extra arguments

Examples

print.IDEMSINGLE

Print MCMC mixing checking result

Description

Print method for class IDEMSINGLE objects generated by imImpSingle

Usage

```
## S3 method for class 'IDEMSINGLE'
print(x, ...)
```

Arguments

```
x A class IDEMSINGLE object returned from imImpSingle
... Additional arguments
```

See Also

```
imImpSingle
```

```
print.summary.IDEMINFER
```

Print survivors only or SACE analysis results

Description

Print survivors only or SACE analysis results

Usage

```
## S3 method for class 'summary.IDEMINFER'
print(x, delta0 = NULL, delta1 = NULL, ...)
```

Arguments

X	A class IDEMINFER list generated by imInfer
delta0	Selected treatment arm 0 sensitivity parameters
delta1	Selected treatment arm 1 sensitivity parameters
	Extra arguments

summary.IDEMDATA

Summary of IDEMDATA object

Description

Summarize the missing data information for class IDEMDATA objects generated by imData.

Usage

```
## S3 method for class 'IDEMDATA'
summary(object, opt = c("misstable", "missid", "trt"), endponly = FALSE, ...)
```

Arguments

object A class IDEMDATA object returned by imData

opt Types of the summarization

- misstable: Summarize the frequencies of each missing pattern
- missid: Summarize the indices of subjects that need imputation, i.e. survivors with functional endpoint missing
- trt: Treatment arms

endponly Logical variable that indicates whether clinical outcomes not used in calculating

the functional outcome are considered as missing and should be imputed. The default is FALSE, indicating that all missing clinical outcomes will be imputed

sequentially

... Extra arguments

Value

A dataframe with frequencies of each missing pattern when opt is misstable.

A vector of indices of subjects that need imputation when opt is missid.

A vector of treatment arms in the data when opt is trt.

See Also

imData

summary.IDEMINFER

Summary of the inference results

Description

 $Summarize\ survivors\ only\ or\ Survivor\ Averaged\ Causal\ Effect\ (SACE)\ based\ on\ the\ imputation\ and\ bootstrap\ analysis$

Usage

```
## S3 method for class 'IDEMINFER'
summary(object, opt = c("survivor", "SACE"), sace.deltas = NULL, ...)
```

Arguments

object A class IDEMINFER list generated by imInfer

opt Types of the summary

survivor: Survivors only analysisSACE: Survivor Averaged Causal Effect

sace.deltas Vector of sensitivity parameters for SACE estimation. If NULL, the values will

be generated based on the standard deviations of the estimated differences in the

functional outcomes between the treatment and control arms

. . . Optional arguments for summary

Details

For SACE, the default sensitivity parameters will be determined by the standard deviation of the treatment effect size on the functional outcomes.

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Value

A class summary. IDEMINFER list containing

deltas imputation sensitivity parameters

n.boot number of bootstrap samples in bootstrap analysis

sace.deltas SACE sensitivity parameters when opt = SACE

rst A data frame with columns

- Delta0: Imputation sensitivity parameter for control arm,
- Delta1: Imputation sensitivity parameter for intervention arm
- SACE_Delta: SACE sensitivity parameter when opt = SACE
- Effect: SACE estimate
- LB: Lower bound of the 95
- UB: Upper bound of the 95
- PValue: p-value when when n.boot > 0 in the IDEMINFER object

References

Chiba Y, VanderWeele TJ (2011). A simple method for principal strata effects when the outcome has been truncated due to death. American Journal of Epidemiology 173(7):745-751.

Examples

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